# NAVAL POSTGRADUATE SCHOOL

**MONTEREY, CALIFORNIA**

# THESIS

**SELF-DIAGNOSTICS DIGITALLY CONTROLLED PACEMAKER/DEFIBRILLATORS: A DESIGN PLAN FOR INCORPORATING DIAGNOSTICS AND DIGITAL CONTROL IN THE SCHEMA OF A PACEMAKER/DEFIBRILLATOR DESIGN**

by

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September 2005

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**13. ABSTRACT (maximum 200 words)**

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This thesis investigates the use of Unified Modeling Language (UML) Diagrams, Object-Oriented Analysis and Design, and Structured Query Language (SQL) to develop the high level architecture of a system to store and retrieve digital/wireless communication information from a pacemaker/defibrillator, or other device, and to alert medical personnel when a person is experiencing problems with their health. It presents the requirements and architectural design of the Self-Diagnostics Digitally Controlled Pacemaker/Defibrillator Device. Applications of the SDDCPDD design concept for military missions are explored.

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Submitted in partial fulfillment of the
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# LIST OF ABBREVIATIONS

| | |
|---|---|
| AF | Array Factor |
| CMOS | Complementary Metal Oxide Semiconductor |
| COTS | Commercial -Off -The -Shelf Items |
| dB | Decibel |
| DBMS | Data Base Management System |
| EMI | Electromagnetic Interference |
| FCC | Federal Communication Commission |
| FDA | Food and Drug Administration |
| ICD | Implantable Cardiac Defibrillator |
| IEEE | Institute of Electrical and Electronics Engineers |
| LAN | Local Area Network |
| MRI | Magnetic Resonance Imaging |
| OOA | Object-Oriented Analysis |
| OOD | Object-Oriented Design |
| OTS | Off the Shelf Software |
| PAM | Pulse Amplitude Modulation |
| QAM | Quadrature Amplitude Modulation |
| RDBMS | Relational Database Management System |
| RFI | Radio-Frequency Interference |
| SDDCPDD | Self-Diagnostics Digital Controlled Pacemaker/Defibrillator Device |
| UML | Unified Modeling Language |
| WAN | Wide Area Network |
| WWAN | Wireless Wide Area Network |
| WWAN | World Wide Area Network |

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First and foremost, I would like to thank Jesus Christ my Lord and Savior for giving me the vision and stamina to stay the course with this idea. I would like to thank Dr. Gappy for giving me the inspiration and encouragement to let me know he thinks my idea is original and unique.  I would like to thank TACOM for giving me the resources and ability to share my idea with individuals in aspects of engineering. I would like to thank Professor William Ray for having the tenacity to abide with the longevity of my research.  I would like to thank Professor Shing for the patience, wisdom, and ceaselessness to see me through. I would like to thanks to all my friends and James for helping me through the thesis process.  I would like to thank my family for allowing me to talk to them until they were bored to tears, and last but not least, thanks to you, Violetta baby, for just being there and telling me I can make it even when I couldn't see the forest because of all the trees.

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# I. INTRODUCTION

This chapter starts with a brief history, followed by a discussion on the areas of research, a list of research questions, methodology of the design, and an explanation of the Self-Diagnostics Digitally Controlled Pacemaker-Defibrillator Device (SDDCPDD) and its operation.

## A. BACKGROUND

Pacemakers and defibrillators have made quantum leaps in capabilities since their technology began over 200 years ago when such pioneers as Luigi Galvani and Alessandro Volta brought about the awareness of electricity, biology, and electro-chemistry. Volta, whose name is synonymous with the rating of batteries (Volts), did remarkable studies in the area of electricity and electrical current. Galvani's observed that nerve/muscle, when stimulated by electrical pulses, caused the muscles to react (move) and triggered a response. Galvani's observations lead him to study the theory of neurophysiology, neurology, and the electrical nature of nerve-muscle function. Galvani and Volta together, created an awareness of such legitimate electrical engineers as Nikola Tesla who had various patents on alternating current, magnetic induction, magnetic field theory, wireless transmission, and wave propagation. In 1947 Dr. Claude Beck defibrillated the first human heart. Dr. John Hopps' concept, innovation and theory of the pacemaker came to acknowledgement in 1949. Hopps led others to become interested in the pacemaker, and several years later (1957-1958) Earl E. Bakker made a breakthrough with the design of the first wearable pacemaker. Other contributions were made by Kouwenoven and Milnor with their 'closed chest capacitor-discharge defibrillator', and Zolls in 1954 with his success on the 'first external defibrillator on the human heart'.

It was not until the advancement of transistor technology that pacemakers became smaller. Transistor technology enabled processors to become an integral part of the pacemaker design, which later allowed the device to become even smaller, software embedded, and implantable. In 1984, pacemaker technology had advanced to the point where a pacemaker was small enough to be implanted into the chest cavity of a human. The first case of this experiment and the implantation in the cavity of a human was done on a premature baby born in Calgary. This became the benchmark for pacemakers, and the very first operation of its kind in the world.

Current pacemakers are very small; about the size of two silver dollars (See. Figure 1.) stacked on top of each other (or two-inches wide and a quarter inch thick), and very easily implanted in a small pocket above the cavity of the chest. The pacemaker also has programmed pacing functions, histogram functions, and shock sensing control algorithms to control the amount of shock needed by the individual. It also has a reprogramming function within the device that allows for reprogramming of the device over the telephone as opposed to going to the doctor. The proposed Self-Diagnostics Digital Controlled Pacemaker/Defibrillator Device (SDDCPDD) will embark on already made and available technology to enhance features, controls, and strategy measures for correcting and enhancing some of the pacemaker/defibrillator current technologies.

**Figure 1. Today's Pacemaker**

## B. AREAS OF RESEARCH

This thesis explores the concept of allowing a pacemaker, defibrillator, or other device (SDDCPDD) to become self-diagnostic, individual specific, serialized, and tagged, therefore, allowing stored information within the device to be sent via SQL to a database, data warehouse, and data store to be maintained for future reference, statistics, and history of a patient's heart pacing defibrillator activities (natural heart rate, chemical composition, and stimulus demands). It also tackles the concept of digital control, wireless communication, database verification, system safety, and security.

## C. RESEARCH QUESTIONS

1. Can software be used to send and update real time information to and from a data warehouse?
2. Can a digital signal be sent via a pacemaker/defibrillator from the human body?
3. Can a digital/wireless communication device cause harm or emit radiation into the body?
4. Can the pacemaker or defibrillator device receive signals from any given place without interference?
5. Can the pacemaker or defibrillator device be used as a transmitter to locate an individual?
6. Can this device be used by the military?

## D. SCOPE OF THESIS

The goal of this thesis is to demonstrate the strength and viability of having a self-diagnostics checker with digital control, and wireless communication to be embedded in a pacemaker/defibrillator device (SDDCPDD). This thesis will discuss the software architecture techniques, robustness, viability and operational requirements of using the SDDCPDD to alert medical or military personnel whenever a patient or military personnel is experiencing problems or need assistance.

## E. METHODOLOGY

The main focus of this thesis is to show how already available Off-The-Shelf software (OTS), and Commercial-Off-The-Shelf Items (COTS) can be used to design a device that has multi-functional uses given the right application and environment. Object Orientated Analysis/Design (OOA/D) is the method chosen to show how the pacemaker/defibrillator device will be used to alert medical personnel whenever a patient is experiencing problems or needs assistance.

## F. CHAPTER OUTLINE

This thesis contains six chapters including the introduction.

Chapter I introduces the purpose of the thesis, its objective, history, areas of research, frequently asked questions, and the methodology of the design.

Chapter II describes the concept of the pacemaker/defibrillator device, its purpose, and system operation.

Chapter III describes the problems associated with the pacemaker/defibrillator design (SDDCPDD), how those problems created a need and how that need is met by formula solutions.

Chapter IV describes the analysis of the SDDCPDD architecture, functionality and operational environment, sequence of events, product requirements, and SQL communication requirements used to satisfy the data transfer of the information to and from the SDDCPDD, and the digital control and wireless communication scheme.

Chapter V gives a brief explanation of issues associated with the integration between the Software/Hardware (SW/HW), OTS, and COTS.

Chapter VI concludes this thesis and summarizes the major points of putting such a device on the market, and focuses on a need for such a device to be used by the military and how it can benefit soldiers in the field.

# II. PACEMAKER/DEFIBRILLATOR OBJECTIVE

## A. INTRODUCTION

This chapter will discuss the concept of the pacemaker/defibrillator device, its purpose, and system operation.

### 1. Pacemaker Concept

#### *a. Definition*

A pacemaker is used when the heart beats too slowly (bradycardia) or has other abnormal rhythms (arrhythmias). In some cases, pacemakers are used to treat the symptoms of heart failure.

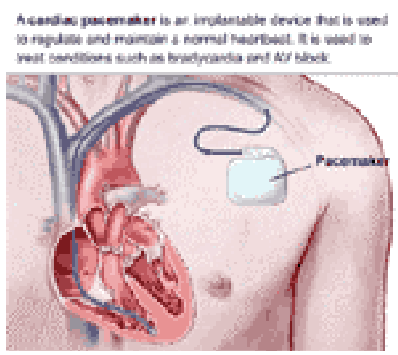


**Figure 2. Pacemaker (Implantable)**

#### *b. Pacemaker Purpose and System Operation*

A pacemaker can restore a normal heart rate so that the heart can pump more effectively. This can reduce or stop the symptoms of abnormal heartbeats (arrhythmias), dizziness, confusion, fainting, or fatigue. A pacemaker consists of a battery and electrical circuitry (pulse generator). The battery powers the pacemaker. The circuitry checks the heart rate and produces tiny electrical pulses that keep the heart beating at the correct pace.

The pacemaker is connected to the heart through one to three insulated wires (leads) that are attached directly to the heart's chambers. Some pacemakers can be customized to meet specific needs.

- **Rate-Responsive Pacemakers** These pacemakers may be programmed to increase or decrease heart rate to match your activities (i.e. resting or walking).
- **Single-Chambered Pacemakers** These pacemakers use only one lead placed into the right upper chamber of the heart (right atrium) or the right lower chamber (right ventricle).
- **Dual-Chambered Pacemakers** These pacemakers have two leads. One is placed in the right atrium, the other in the right ventricle.
- **Cardiac Resynchronization Therapy Pacemakers** These pacemakers have three leads. One is in the right atrium, one is in the right ventricle, and one is placed through the heart's veins to the left ventricle.

## 2. Defibrillator Concept

### *a. Definition*

An implantable cardioverter defibrillator (ICD) is a device that monitors heart rhythms, and delivers shocks if dangerous rhythms are detected.

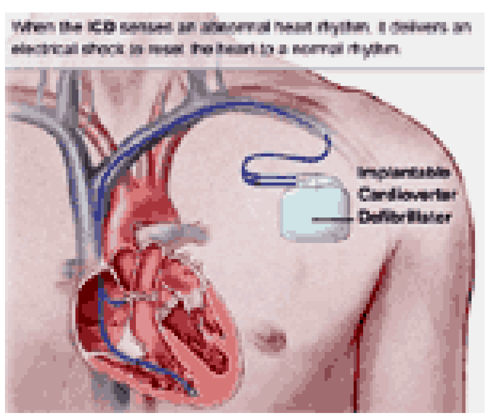


**Figure 3. Defibrillator (Implantable)**

### *b. Defibrillator Purpose and System Operation*

Stopping the potentially fatal fibrillation is called *defibrillation*. The ICD's mission is to 'protect against sudden cardiac death from ventricular tachycardia and ventricular fibrillation'. The defibrillator is similar to the pacemaker except, it delivers an electrical shock when the heartbeat becomes erratic. The ICD continuously checks the heart rate. When it detects a too-rapid or irregular heartbeat, it delivers a shock that resets the heart to a more normal rate and electrical pattern (cardioversion).

Many ICDs record the heart's electrical patterns whenever an abnormal heartbeat occurs. The SDDCPDD will operate on the same principle. 'Doctors can then review the patient's records before and during regular check-ups'. The SDDCPDD will both record and send information to the doctor's office to be analyzed by the doctor and when a situation becomes serious enough to warrant an unscheduled doctor's visit, the doctor will either contact the individual to come in immediately or reset the parameters of the individual's SDDCPDD to the new conditions that the cardiologist sees as appropriate remotely via wireless communication.

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# III. PROBLEMS ASSOCIATED WITH PACEMAKERS/DEFIBRILATORS

## A. PROBLEM

### 1. Problem Statement

| | |
|---|---|
| **The Problem of** | **90 of its pacemakers being used by heart patients could stop emitting the electrical signals that regulates heartbeat.** |
| **Affects** | **patients/users, programmers, doctors, cardiologists, software engineers, and system design engineers.** |
| **The result of which** | **will help eliminate misdiagnosed system function, determine the mean-time between failures (MTBF), allow a faster response time for diagnosis, allow the doctors, cardiologist, software engineers, design engineers, and programmers to assess which component or part of the system is at fault.** |
| **A successful solution would** | **allow for better detection of common faults within the design itself, allow for advanced control and monitoring of patients conditions, allow the doctor to be able to call and alert the patient that there is a problem with their device, and determine whether or not they need to come into the doctors office, hospital, or be scheduled for an immediate appointment.** |

**Table 1. Problem Statement**

I came across several articles that talked about the problems associated with the design, however, the one that prompted me the most about coming up with a solution to the problem of the pacemaker/defibrillator design was an article written in the Annals of Internal Medicine by David Hayes and Ronald E. Vliestra. In their article they stated 'the electrocardiographic signs of pacemaker malfunction can be grouped into four categories: failure to output, failure to capture, under sensing, and inappropriate pacemaker rate. For each of these categories, there may be true malfunctions and pseudomalfunctions. In addition, environmental sources of electromagnetic interference, both within and outside the hospital environment, can result in pacemaker malfunction.' These problems are sometimes critical to the patient and therefore should be eradicated. The SDDCPDD has to be reliable. A reliable system is a system that still 'functions satisfactorily for a prescribed time and under stipulated environmental conditions'. A safety-critical system such as the SDDCPDD is considered as being a software-intensive, and moreover, since most accidents arise in the interfaces and interactions among components, software plays a direct and important role in system safety and must be an integral part of the system design and safety efforts. This is why the SDDCPDD, within the granularities of its design constraints and conditions, has to let everyone from the user to the cardiologist, and everyone in between, know when an error occurs with the design (see Figure 4.). The SDDCPDD is intended to operate in a condition that would lessen the hazardous conditions associated with the system operation.

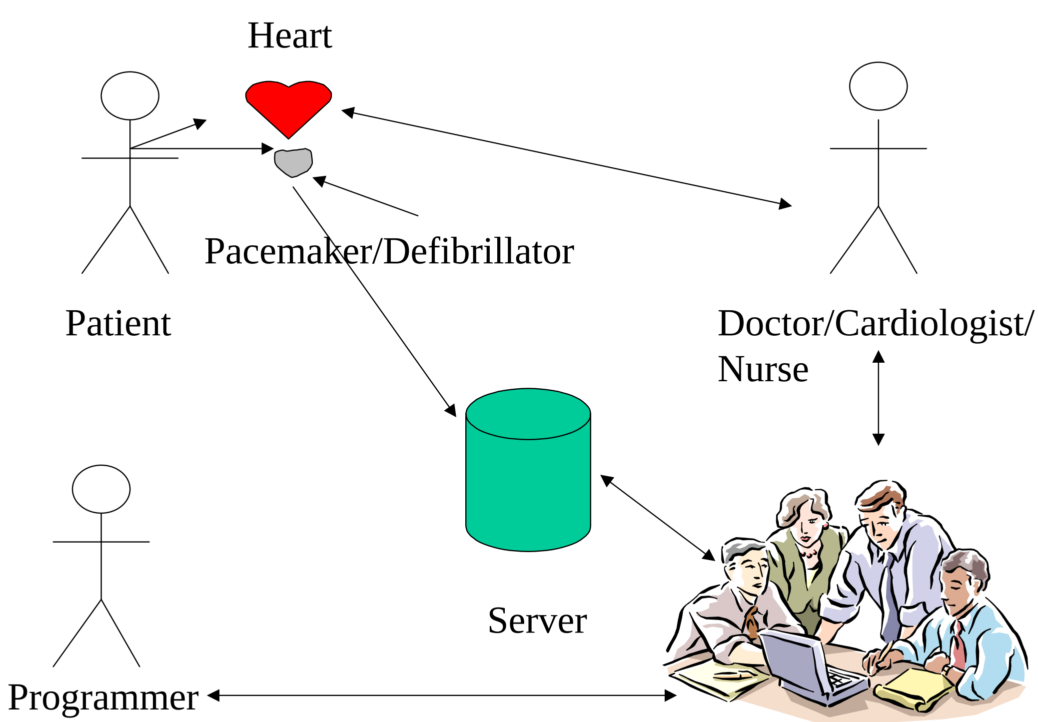


**Figure 4. SDDCPDD Interaction Diagram**

## 2. Problems Encountered by the Pacemaker/Defibrillator Device and How They Affect Its Operation.

### *a. The Role of EMI, Ultrasonic, and Ionizing Radiation Interference*

Electromagnetic, Ultrasonic, and Ionizing Radiation Interference still has an agonizing affect on pacemaker/defibrillator devices. The longer people with a pacemaker/defibrillator devices are exposed to or in contact with these types of phenomenon the greater the chance these devices could drastically or critically affect their well being.

Devices such as cellular telephones, radiation emitting devices (radiotherapy), Magnetic Resonance Imaging (MRI), Lithotripsy (shock treatment), electromagnetic fields and other appliances that have motors emit large amounts of current that have caused problems with the pacemaker/defibrillator device. Most modern day pacemakers have corrective counter measures to combat some of these problems.

The National Association for Amateur Radio submitted an article on the web that said 'The successful design of modern pacemakers will ensure that most patients experience few or no problems'. Nevertheless, if a patient is in close proximity to any of these sources, then the 'pacemakers will respond in a variety of ways':

- Erratic pacing rate, or
- Rate increase
- Noise reversion/asynchronous pacing (where the pacemaker paces the heart at a fixed rate)
- A single beat inhibition (where the pacemaker may not pace the heart for a single cardiac cycle)

They also stated that 'all of the problems that can occur within the pacemaker are solvable by simply moving away from the equipment that presents the danger'.

The time it takes to affect the device is dependent on the strength of the MRI machine, magnetic field, or magnet. Location and devices that cause these problems are:

- MRI machines in hospitals
- Large generators, such as those used in the power industry
- Induction furnaces, such as those used in steel industries
- Nearness to powerful large loudspeakers
- Electromagnets used in car wrecking yards

Magnetic Resonance Imaging (MRI) has the most harmful effect on today's pacemakers. An article published by the Annals of Internal Medicine stated that 'powerful static, time-varying magnetic, and radiofrequency fields of the magnetic resonance imaging (MRI) system can affect normal pacemaker operation and function. At the least, exposure to MRI causes all pacemakers to revert to an asynchronous mode because of reed-switch closure.' The article also stated that 'this effect can be avoided only in pacemakers in which the magnet response can be programmed "off." Investigations of the interaction between MRI and the pacemaker have shown that the MRI machine does not permanently damage the reed switch or other pulse generator components;' for this reason the SDDCPDD has a program checker to ensure that the program is working within its correct parameters set by the programmer/cardiologist. If the SDDCPDD was programmed to sense radiation levels, and then automatically set itself to "off" when levels are too high, and when it becomes apparent that a pacing or defibrillator response is needed, then the pacemaker/defibrillator or SDDCPDD device will resume by turning itself on and then perform the pacing or defibrillator function called upon by the patient's condition. Another problem of concern with the current device is that the radiofrequency pulse period may be set at extremely short intervals for some diagnostic procedures (available range of 20 to 2000 ms). 'Patients with susceptible pacemakers theoretically could be paced at rates as high as 3000 beats/min when exposed to these types of phenomenon for a long period of time during these procedures'.

Another device that should be used with caution is the transthoracic defibrillation because it could cause problems to a pacemaker if (1) the person performing the procedure is not aware that the person receiving the shock has a pacemaker, or (2) the person performing the procedure is unaware that the 'defibrillation paddles should be positioned anteroposteriorly and as far from the pacemaker or leads as possible.'

### *b. Radiation Emitting to, from and around the Device*

There are certain levels of radiation that must be avoided in order to prevent damage or failure to the cardiac pacemaker/pulse generators. CMOS devices provide some prevention, however, in recent years there has been publicity, speculation, and concerns over claims of possible health effects due to RF emissions from hand-held wireless telephones having caused problems to both people and pacemakers. The SDDCPDD, like the cellular telephone, will have to be investigated to see if it causes a problem when updating and sending information because it operates under the same principle as the cellular telephone.

Research organizations funded by the cellular industry and wireless equipment manufacturers, have been investigating potential health effects from the use of hand-held cellular telephones, and other wireless devices, especially with respect to concerns that they might cause cancer.

There is no scientific evidence that supports claims that wireless cell phone usage causes cancer. There is no evidence to support assertions that cell phone usage causes headaches, dizziness, or memory loss, or is a real concern regarding pacemaker/defibrillator devices. This is promising for the SDDCPDD, however close monitoring and investigations will have to be done to determine whether or not wireless transmission coming from the device will cause cancer or harm to the body. Studies are ongoing and key government agencies, such as the Food and Drug Administration (FDA), continue to monitor the results on the latest scientific research on this topic. The World Health Organizations has also established an ongoing program to monitor research in the effects of cell phone usage and ‘will make recommendations’ on issues of concern. Furthermore, the FCC's exposure guidelines specify limits for human exposure to RF emissions from hand-held mobile phones in terms of Specific Absorption Rate (SAR). SAR is a measure of the rate of absorption of RF energy by the body. The allowable or safe limit for persons using a mobile phone is a SAR of 1.6 watts per kg (1.6 W/kg), and is considered as being the average power of Watts over one gram of tissue. Compliance with this limit must be demonstrated before the FCC approves or grants the use of cellular telephones for marketing in the United States. Somewhat less restrictive limits, e.g., 2 W/kg averaged over 10 grams of tissue, are specified by the ICNIRP (International Commission on Non-Ionizing Radiation Committee) guidelines used in Europe and some other countries.

If the transmission of the digital signal or radiation being sent from the SDDCPDD/pacemaker/defibrillator device is less than 1.6 W/kg per one gram of tissue and not to exceed 2 W/kg over 10 grams of tissue then the device should be safe from causing harmful radiation effects to the body.

Measurements and analysis of SAR in models of the human head have shown that the 1.6 W/kg limit is unlikely to be exceeded under normal conditions of use of cellular and PCS hand-held phones. The same can be said for cordless telephones used in the home. Testing of hand-held phones is normally done under conditions of maximum power usage, thus providing an additional margin of safety. This is excellent, since most phone usage is not at maximum power.

The SDDCPDD, like the cellular telephone, has to send signals or information on carrier waves using some of the same frequencies. Cellular radio services transmit frequencies between 800 and 900 megahertz (MHz). Transmitters in the Personal Communications Service (PCS) use frequencies in the range of 1850-1990 MHz. Antennas used for cellular and PCS transmissions are typically located on towers, water tanks or other elevated structures including rooftops and the sides of buildings. The combination of antennas and associated electronic equipment is referred to as a cellular or PCS "base station" or "cell site." A cellular base station may utilize several "omni-directional" antennas that look like poles. These poles are 10 to 15 feet in length, and are becoming less common in urban areas.

### 3. Common Solutions to Fix the Problems

Since the Food and Drug Administration (FDA) involvement in trying to come up with a standard frequency for medical devices, the decrease of interrupted signal transmission and distortion has become less than it was before their involvement. The FDA has made a standard for certain types of medical devices to operate on bandwidths of frequencies that are only associated with and allowed on medical devices. This is done to keep radio interference and other types of inferences from distorting signals of the medical devices. The FCC’s Wireless Medical Telemetry Service (WMTS) Reports, and sets aside the frequencies of: 608 to 614 MHz, 1395 to 1400 MHz, and 1429 to 1432 MHz for primary or co-primary use by eligible wireless medical telemetry users. This action creates frequencies that will have devices to be banned to certain ranges and therefore protected against interference from other in-band RF sources.

The FCC’s definition for wireless medical telemetry is consistent with recommendations made in April 1999 by the American Hospital Association (AHA) Task Group on Wireless Medical Telemetry. The military uses frequencies in certain bandwidths that should not be used by medical telemetry devices. Anyone using high frequencies or not sure what frequencies they intend to use on their device, should contact the military to see if the frequency being used or about to be used interferes with the frequency of their medical device.

This is why it is advisable to coordinate with the government (primarily military) if you are transmitting signals within 80 km of some radio astronomy facilities and within 32 km of other radio astronomy facilities. ‘The new FDA and FCC regulation mandates that all new wireless medical telemetry devices operate in the band of frequencies from 450 – 460 MHz by January 29, 2001. It also mandated that high-power and mobile user applications operate in the band of frequencies from 460 – 470 MHz, having to conform by 2004. This effort seeks to minimize the potential for EMI in medical telemetry devices.'

## B. NEED

### 1. Patient Need Statement

There is a need to have a pacemaker/defibrillator that provides both a self-system diagnostic check as well as a method of providing a signal to the doctor's office in times when the patient is experiencing problems with his or her pacemaker/defibrillator/SDDCPDD.

### 2. Meeting the Need

The need can be met by proposing solutions and making provisions to fix the design constraints and limitations on previously used devices. Modeling and simulation can be used to analyze and verify methods in the design. It will be used to test the device to make sure it is applicable and safe for use. It will also help prove the viability and robustness of the system and its usage.

# IV. SDDCPDD ARCHITECTURE

## A. INTRODUCTION

The SDDCPDD Architecture is a high-level architecture and it will be used for the purpose of this thesis as a mechanism to show the way in which all the components or entities within the SDDCPDD will operate. The Self-Diagnostics Digital Controlled Pacemaker/Defibrillator Device (SDDCPDD) Architecture is composed of off the shelf software and hardware items to embark on correcting faults found with current pacemaker/defibrillator technologies. The architecture will show how the system will store and retrieve digital/wireless communication information from a pacemaker/defibrillator, or other device, and to alert medical personnel when a person is experiencing problems with their health. It will also convey the functionality and operational environment, sequence of events, product requirements, and SQL communication requirements used to satisfy the transfer of data to and from the SDDCPDD.

## 1. SDDCPDD Deployment Diagram

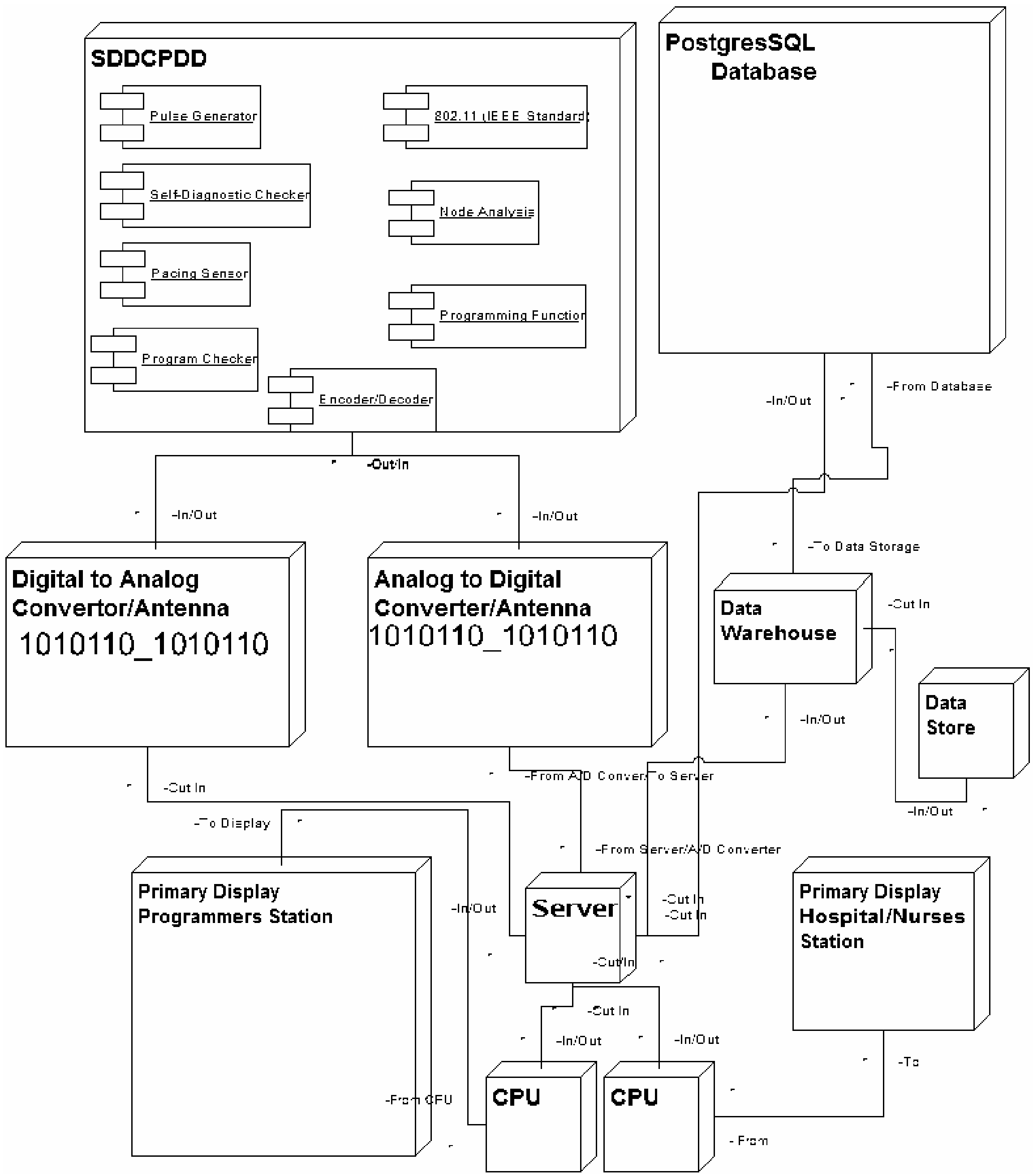


**Figure 5. SDDCPDD Architecture – Deployment Diagram**

## 2. SDDCPDD Architecture Description

| Name | Description | Actor(s) |
|---|---|---|
| Patient | Experiences irregular heartbeat. | SDDCPDD |
| Self-Diagnostic Checker | Checks leads, voltage levels, and circuitry for discontinuity. | Node Analysis |
| Pacing Sensor | Senses a problem with the heart and performs an operation to correct the heart rhythm from either beating to fast, slow, or not at all. | Pulse Generator |
| 802.11 (IEEE Standard) / Server/Modem | The SDDCPDD sends out or receives a signal via digital/WWAN signal transmission/processing to or from a hospital, or doctors office. | Analog to Digital Converter /Digital to Analog Converter/ Encoder/ Decoder/ |
| PostgresSQL | Stores the patient's information and allows for updates of records | Database/Data Warehouse/Data Store |
| Error Messaging | If an emergency happens (something goes wrong with heart, pacing, program, test, sensor, circuit) where the individual needs immediate attention an audible alert will go off at the nurse's station. | Alarm |
| Calibration / programming | Is performed by the programmer via wireless communication, or by an appointment at the hospital, with the cardiologist, or doctor's office, and by regular phone or cell. | Programmer |

**Table 2. Use Case Component Description**

## B. SDDCPDD PRODUCT REQUIREMENTS

The product content in this section is referred to as Functionality, Usability, Reliability, Performance, and Supportability (FURPS), and its purpose is to identify the attributes of the SDDCPDD Device.

### Functionality

1. The processor will verify the bytes received equals the bytes sent, and vice versa.
2. The device will be protected from severe memory leakage.
3. The battery must last for approximately 10 years or greater.
4. The system must have a fault-tolerant mechanism.
5. The SDDCPDD must be able to function at high and low altitudes.
6. The SDDCPDD must be tolerant to EMI and RFI.
7. The SDDCPDD must be able to send the patient’s stats to the hospital, doctor’s office, nurse’s station, cardiologist and programmer in cases requiring immediate attention or action
8. The SDDCPDD must be protected against software runaway.
9. The SDDCPDD will send an error message to the nurse’s station when the patient warrants immediate attention.
10. The patient’s information must be displayed on the screen at the nurse’s station until a nurse, doctor, cardiologist, programmer, or other authorized person has acknowledged that patient X has a need for immediate attention.

### Usability

1. The record must be updated each time a patient’s information is sent to the doctor’s office.
2. The software used must be supportable.
3. The SDDCPDD needs to communicate with the process computers, service stations, and operating and monitoring computers.
4. The SDDCPDD must be scalable to support a large range of products.
5. The SDDCPDD must be programmed via wireless communication

6. The software must monitor and record all SDDCPDD events when signals are sent and received by the hospital, programmer, cardiologist, nurse's station, or doctor.

**Reliability**

1. The information must be displayed on a screen at the hospital, nurse's station, doctor's office, programmer or cardiologist's office until a receipt of action is acknowledged.
2. The modems must encode/decode the signal and store it into the database.
3. The SDDCPDD must support redundancy.
4. The pulse generator must be able to be reprogrammed via wireless communication, cell phone, regular phone, or by computers in the hospital, doctor's office, and/or cardiologist's office.
5. The SDDCPDD after receiving information to be encoded will verify that the bytes received is equivalent to the bytes sent.
6. The self-diagnostic checker checks the internal programming of the SDDCPDD, voltage levels, continuity, and communication points every 84 hours, and/or after every event.
7. The SDDCPDD must respond to irregularities within 1 ms if the response of the heart is outside its normal bounds.
8. The Alarm at the nurse's station or doctor's/cardiologist's office will sound until there is an interaction with a nurse, doctor, programmer or cardiologist.

**Performance**

1. The SDDCPDD must continue to send information until the receiving end receives an acknowledgement from the SDDCPDD.
2. All execution timing sequences, Rate Monolithic Analysis (RMA's), instrumentations, and controls are deterministic.

**Supportability**

1. The software/hardware interface interactions must be supportable, interchangeable, and maintainable.

## C. USE CASE DIAGRAMS/USE CASES/SEQUENCE DIAGRAMS

The use case diagrams in these subsequent pages will be used to explain the proposed process of how the user interacts with the SDDCPDD, and how the SDDCPDD interacts with the programmer, self-diagnostic checker, and the doctors, cardiologists, and nurses at the nursing station. The function of the use cases is to describe in words how the actors or objects interact with one another. This analysis explains the action 'taken, who initiates it, what the appropriate responses are, and what kinds of things can go awry. The sequence diagrams show the sequence of messages, (implicit) inactive periods, and scenario annotations between objects.'

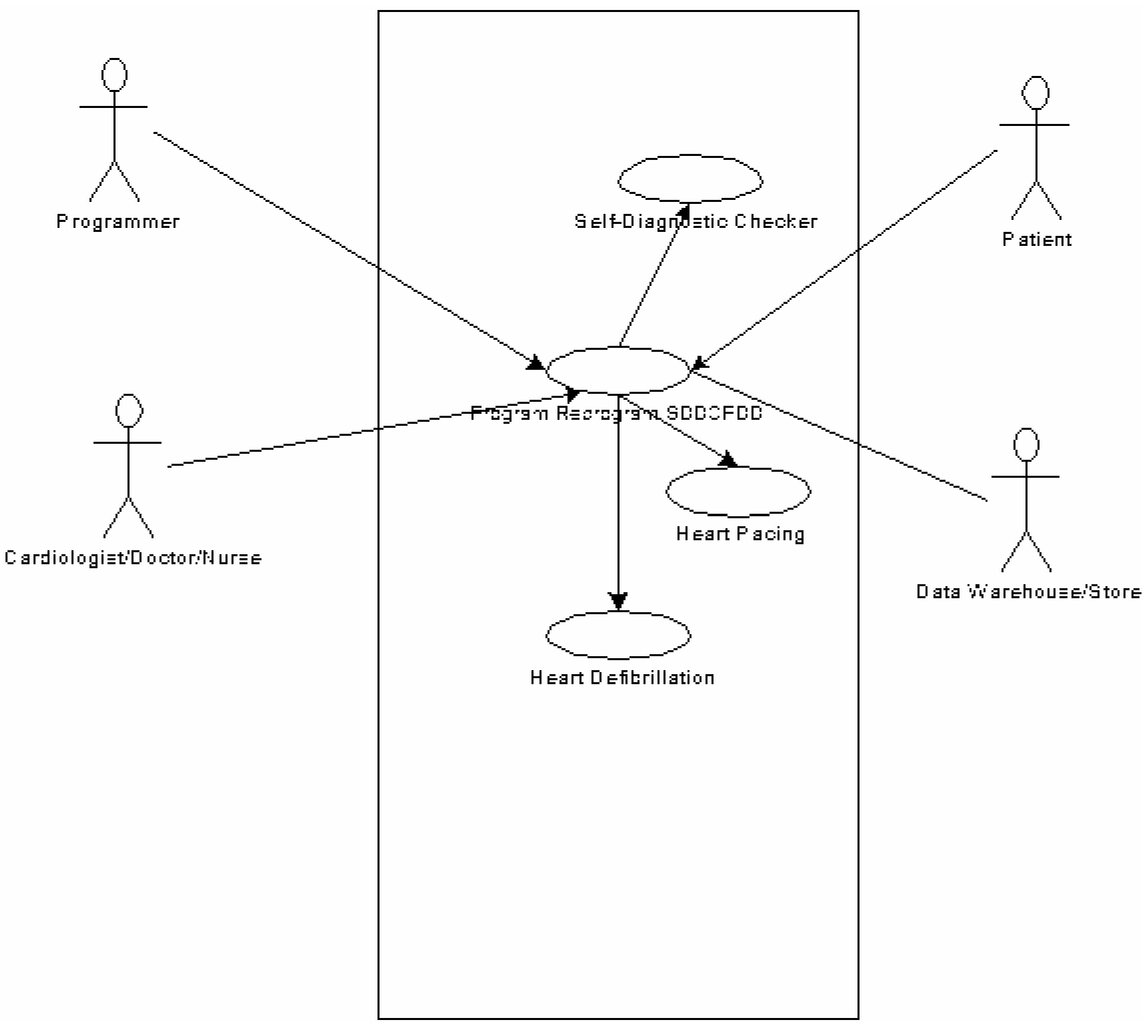


**Figure 6. SDDCPDD - Use Case Diagram**

## D. SDDCPDD DESCRIPTION AND ENVIRONMENT

### 1. SDDCPDD Programming

#### *a. Use Case*

| | |
|---|---|
| Use Case Name: | Program SDDCPDD |
| Iteration: | Finished |
| Actors: | Programmer, Database, Data Warehouse, Data Store |
| Summary: | The programmer programs the patient's SDDCPDD to the conditions set by the cardiologist. |
| Basic Course of Events: | 1.The programmer sets the SDDCPDD to a max refractory period of 200 ms, at a rate of 75 bpm, a pulse width of 5ms, and a pulse amplitude of 3.5V, and shock rate of 31 J per shock rate at a 2 J shock rate increase.<br>2. The SDDCPDD triggers the heart pacing sensor.<br>3. The SDDCPDD triggers the self-diagnostic checker.<br>4. The self-diagnostic checker checks the system.<br>5. The SDDCPDD stores the information and sends the data, diagnostic results and patients stats to the database/data warehouse/ data store.<br>6. The programmer checks the database to see if the patient data/stats are in the database.<br>7. The programmer tells the patient that his/her information is loaded in the database and that he/she can resume normal everyday activities. |
| Alternative Paths: | 6a. Within 1 μs a response comes back indicating that the data was not loaded in the database:<br>1.The programmer reprograms the SDDCPDD<br>2.Repeat Steps 2-6. |
| Exception Paths: | The programmers tasks are completed upon verification that the patient's information has been loaded in the database. |
| Preconditions: | The cardiologist and programmer have already agreed upon the conditions and stats that need to be programmed into the patient's SDDCPDD. |
| Assumptions: | None |
| Postconditions: | None |
| Author: | Steven Nedd |
| Date: | May 24, 2005--Facade |

**Table 3. Program SDDCPDD – Use Case**

### *b. Sequence Diagram*

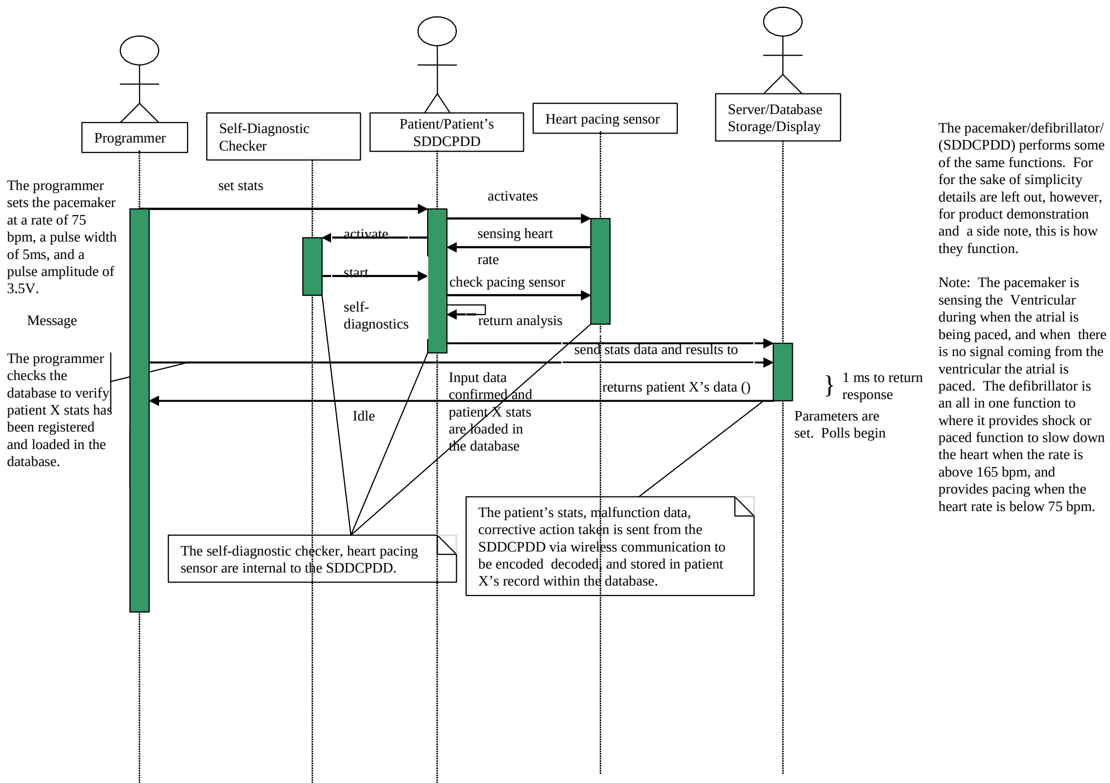


**Figure 7. Program SDDCPDD – Sequence Diagram**

## 2. SDDCPDD Heart Pacing

### *a. Use Case*

| | |
|---|---|
| Use Case Name: | **Heart Pacing** |
| Iteration: | **Finished** |
| Actors: | Patient, Database, Data Warehouse |
| Summary: | Patient X's heart beat drops from normal (75 bpm) to 50 bpm. The SDDCPDD heart pacing sensor acknowledges that the bpm has dropped to a level that is abnormal and begins to intervene by sending a signal to the SDDCPDD to begin the pacing function to ramp-up the heart rate to 75 bpm. After the heart rate reaches it's normal pacing rhythm the event and the corrective action will be sent to the database, and then stored in the data warehouse/ data store. |
| Course of Events: | 1. The pacing sensor senses that the heart rate has dropped below normal.<br>2. The SDDCPDD begins to activate the pacing function and increases the heart rate to a rate of 75 bpm.<br>3. After the heart reaches its normal rate the event as well as the corrective procedures are stored in the database/data warehouse/ data store. |
| Alternative Paths: | 2a. If the SDDCPDD does not respond to the signal to increase the pacing rate, the sensing mechanism will keep sending the signal up to three tries, and then if it still does not respond then it will cause the SDDCPDD to reset itself.<br>2b. If the pacing function still does not respond, the sensing mechanism will trigger a signal to both the self-diagnostic checker and the SDDCPDD, the SDDCPDD will then send a signal to both the database/data warehouse/data store and to the nurse's/cardiologist's/doctor's/programmer's station. Upon receiving the signal at the nurses station, the nurse/ cardiologist/programmer/doctor will give the patient a call immediately and have him to come in for an appointment to adjust or correct the problem acknowledged by the self-diagnostic checker. |
| Exception Paths: | None |
| Assumptions: | The SDDCPDD provides both pacing and defibrillating functions. The diagnostic checker checks the system and sends the analysis to the database/data warehouse/data store. |
| Preconditions: | None |
| Postconditions: | None |
| Author: | Steven Nedd |
| Date: | May 25, 2005--Facade |

**Table 4. Heart Pacing - Use Case**

## *b. Sequence Diagram*

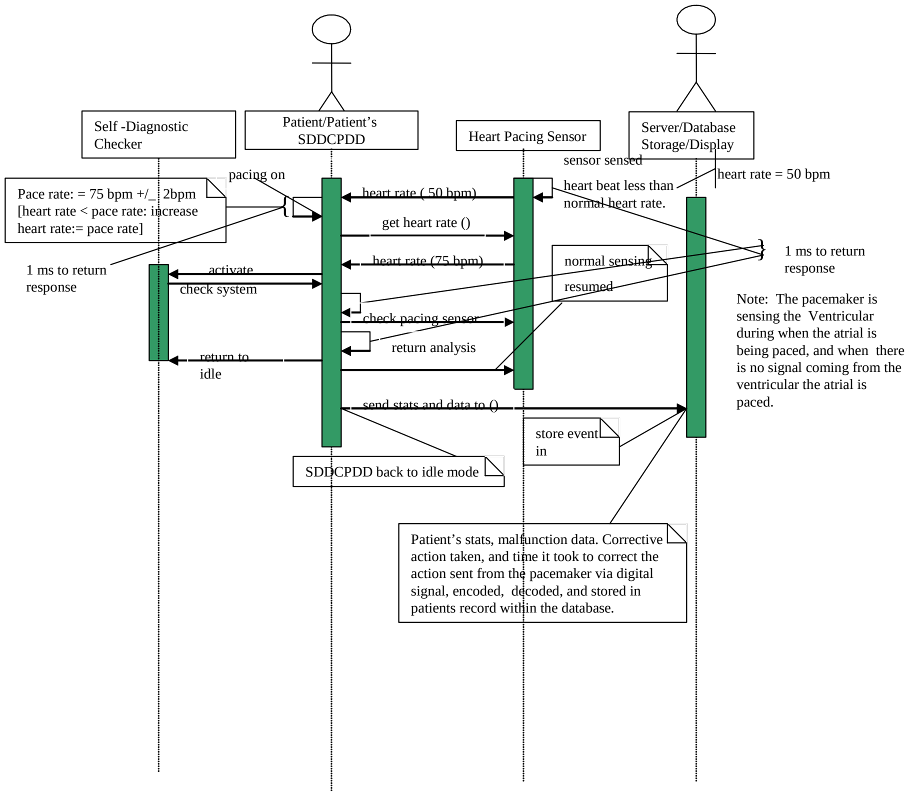


**Figure 8. Heart Pacing – Sequence Diagram**

### 3. SDDCPDD Heart Defibrillation

#### *a. Use Case*

| | |
|---|---|
| Use Case Name: | **Heart Defibrillation from the SDDCPDD** |
| Iteration: | **Finished** |
| Actors: | Patient, Database, Data Warehouse, Data Store |
| Summary: | The heart pacing sensor senses an abnormal heart rate of 185 bpm. The SDDCPDD administers a shock energy level starting form 31 J (Joules) and increases the shock energy level to 41 J at a shock rate of 2 J per shock pulse to get the heart to resume a normal heart rate of 75 bpm. |
| Course of Events: | 1. The pacing sensor senses the patients heart rate has increased from 75 bpm to 185 bpm.<br>2. The defibrillator administers a shock level of 31 J to get the heart to stop, and then resumes normal pacing.<br>3. The heart pacing sensor senses the heart rate.<br>4. The heart pacing sensor senses the heart has resumed normal pacing and the heart rate is at 75 bpm.<br>5. The SDDCPDD signals the diagnostic checker to check the system.<br>6. The diagnostic checker checks the system and sends the response to the SDDCPDD.<br>7. The SDDCPDD sends the event and corrective action to the database/data warehouse/data store. |
| Alternative Paths: | 3a. If the pacing sensor senses the heart rate has not returned back to it's normal pacing of 75 bpm after the SDDCPDD has repeated step 2 until it reaches 41 Joules, the SDDCPDD will then send a signal to the nurse's station to alert them that patient X's heart has failed and needs immediate rescue. |
| Exception Paths: | None |
| Assumptions: | None |
| Preconditions: | Stress was the cause of the abnormal heart rate. |
| Post conditions: | One shock was all that was necessary to resume the heart to its normal rhythms. |
| Author: | Steven Nedd |
| Date: | May 25, 2005--Facade |

**Table 5. Heart Defibrillation - Use Case**

### b. *Sequence Diagram*

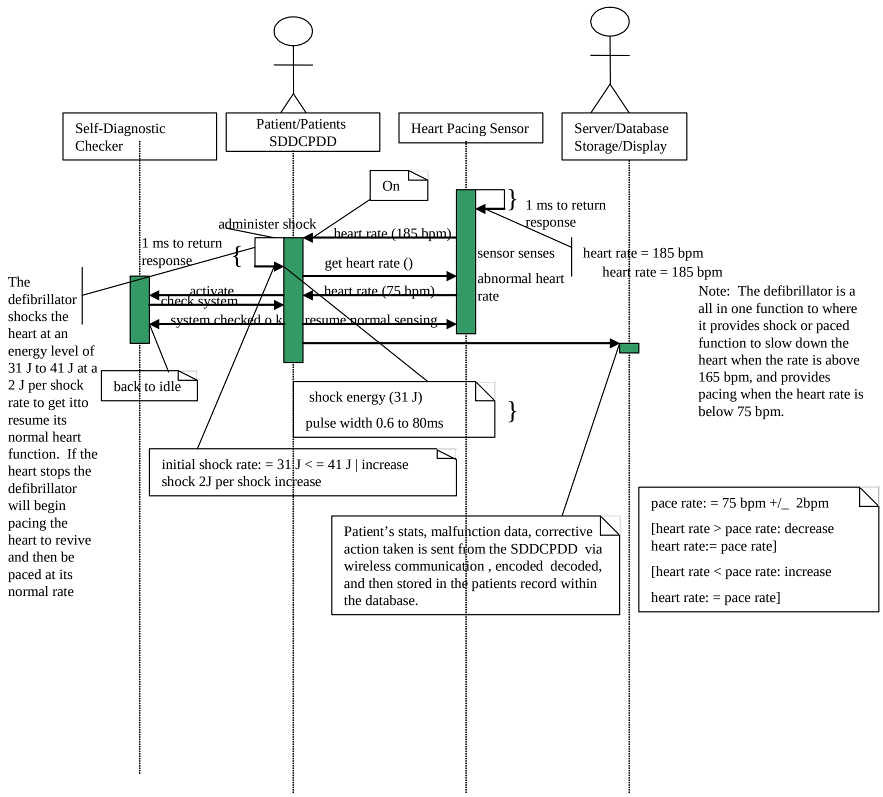


**Figure 9. SDDCPDD Defibrillation – Sequence Diagram**

### 4. SDDCPDD Self-Diagnostics Checks

#### *a. Use Case*

| | |
|---|---|
| Use Case Name: | Self-Diagnostic Checks of the SDDCPDD |
| Iteration: | Finished |
| Actors: | Database, Data Warehouse, Data Store |
| Summary: | Every 84 hours the self-diagnostic checker checks the system for proper operational functionality, proper voltage levels, continuity, proper operation and then sends the information to the database/data warehouse/data store. |
| Course of Events: | 1. At the 84th hour of operation, the diagnostic checker checks the SDDCPDD for proper functionality.<br>2. The SDDCPDD performs a self-check for proper voltage levels.<br>3. The SDDCPDD then checks the system for continuity between all points and connections.<br>4. The SDDCPDD then checks the internal program within the SDDCPDD, and communication points for a system level check.<br>5. The SDDCPDD then sends the results to the database/data warehouse/data store to be maintained for future history. |
| Alternatives Paths: | 2a. If the voltage level is lower than what is required by the system to properly function the SDDCPDD will send this fault to the nurse's/doctor's/programmer's/ cardiologist's station to alert them that patient X needs to come in and have his/her SDDCPDD serviced.<br>3a. If the self-diagnostic checker finds a fault due to discontinuity, then the SDDCPDD will send this fault to the nurse's/doctor's/programmer's/cardiologist's station to alert them that patient X needs to come in and have his/her SDDCPDD serviced.<br>4a. If there is a system problem with the SDDCPDD, the SDDCPDD will send a signal to the nurse's/doctor's/ cardiologist's station to alert them that patient X needs to come in and have his/her SDDCPDD serviced. |

**Table 6. Self-Diagnostic Checker – Use Case**

| | |
|---|---|
| Extension Points: | The nurse, doctor, cardiologist, or programmer accurately determines the possible fault by checking the database. |
| Assumptions: | The self-diagnostic checker is embedded in the SDDCPDD. Every 84 hours is a random number used to illustrate the capabilities and features that this device will be utilizing. The next check will be at 178 hours and so on every 84 hours. The SDDCPDD sends the faults, voltage levels, and patient's information to the nurse's/doctor's/cardiologist's station to alert them of the problem. |
| Preconditions: | The clock mechanism automatically triggers the self-diagnostic checker to turn on every 84 hours. |
| Postconditions: | The diagnostic checker goes to idle after the sequence of self-diagnostic checks are completed. It will automatically turn on as soon as the pacing sensor senses an event, or on the $84^{th}$ hour. |
| Author: | Steven Nedd |
| Date: | May 25, 2005 |

**Table 6. Self-Diagnostic Checker – Use Case (continued)**

### b. Sequence Diagram

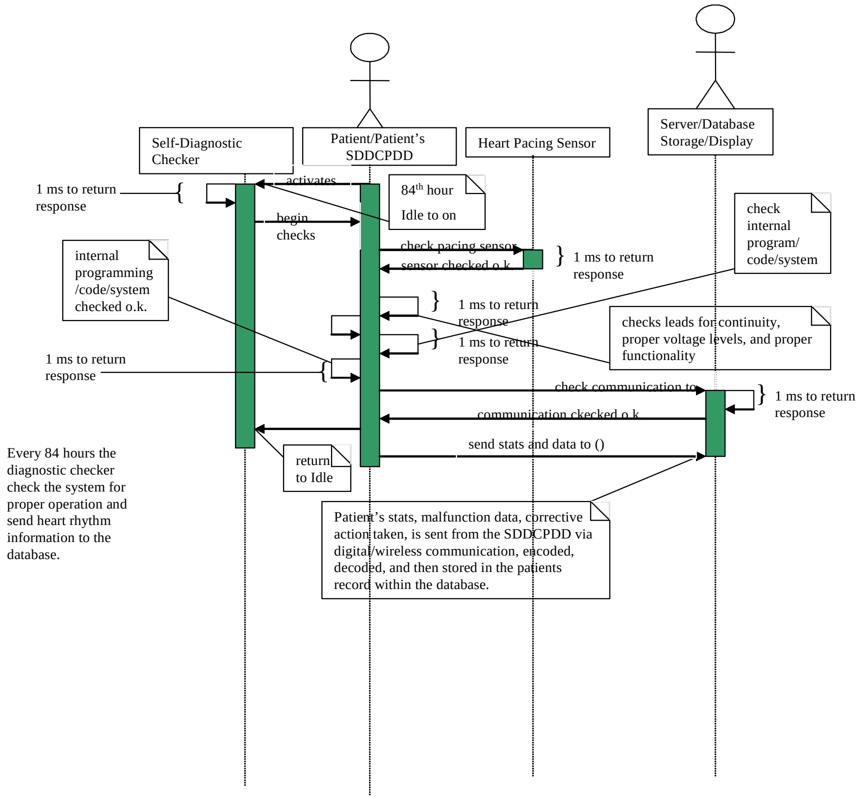


**Figure 10. SDDCPDD Self-Diagnostic Check – Sequence Diagram**

### 5. SDDCPDD Reprogramming

#### *a. Use Case*

| | |
|---|---|
| Use Case Name: | **Reprogram SDDCPDD via Wireless Communication** |
| Iteration: | **Finished** |
| Actors: | Programmer, Cardiologist, Database, Data Warehouse, Data Store |
| Summary: | The diagnostic checker notices that the program within the SDDCPDD has been corrupted. |
| Course of Events: | 1. The SDDCPDD sends a signal to the nurses station to alert them that the program within patient X's SDDCPDD has been corrupted.<br>2. The on duty nurse receives the information and has a cardiologist and/or a programmer working on shift look at patient X's information.<br>3. The cardiologist asks the programmer to call patient X and ask him/her if he/she wants to come in or have his/her SDDCPDD reprogrammed from where he/she is.<br>4. The patient asks the programmer to send the information via wireless means. (End of Event 1. Figure 11.)<br>5. The programmer reprograms patient X's information from the hospital. (Start of Event 2. Figure 12.)<br>6. The programmer checks the database to make sure the patient's information has been properly stored in the database.<br>7. The programmer calls patient X and lets him/her know that his/her SDDCPDD has been reprogrammed and operating as normal. |
| Alternative Paths: | 4a. If the patient chooses to come in the office rather than have the SDDCPDD programmed via wireless communication then the patient's stats will be programmed in the hospital, doctor's office, cardiologist's office, etc. or wherever it is feasible. |
| Assumptions: | Strong magnetic fields caused the SDDCPDD to become corrupted. |
| Preconditions: | The Self-Diagnostic Checker is embedded in and triggered by the SDDCPDD. |
| Postconditions: | The patient SDDCPDD was successfully reprogrammed via wireless communication from the hospital. |
| Author: | Steven Nedd |
| Date: | May 25, 2005--Facade |

**Table 7. Reprogram SDDCPDD - Use Case**

### *b. Sequence Diagram*

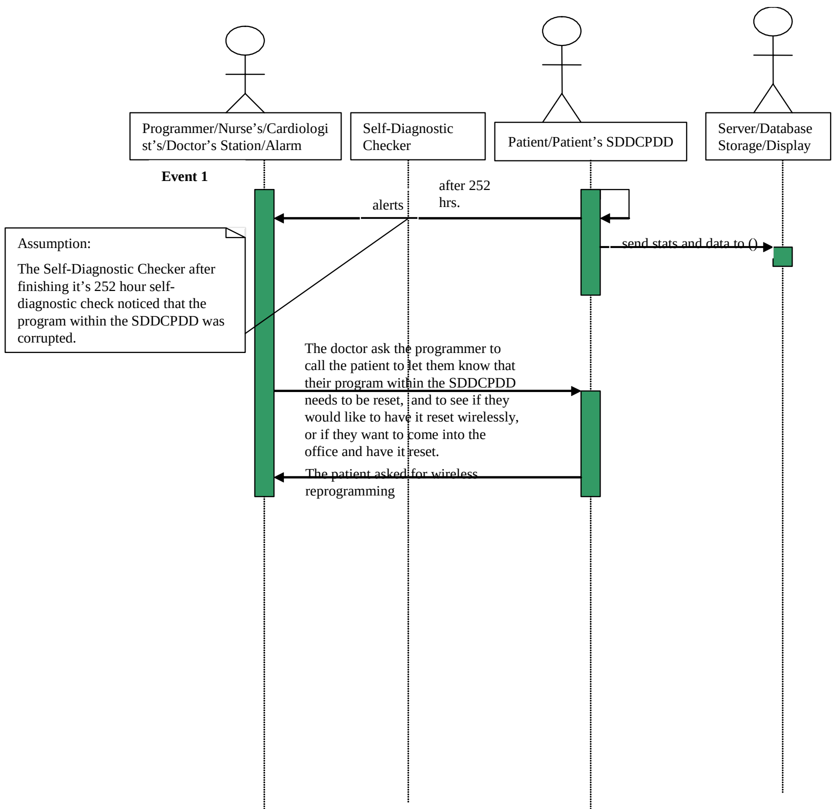


**Figure 11. Reprogram SDDCPDD (Alert Nurse's Station) – Sequence Diagram**

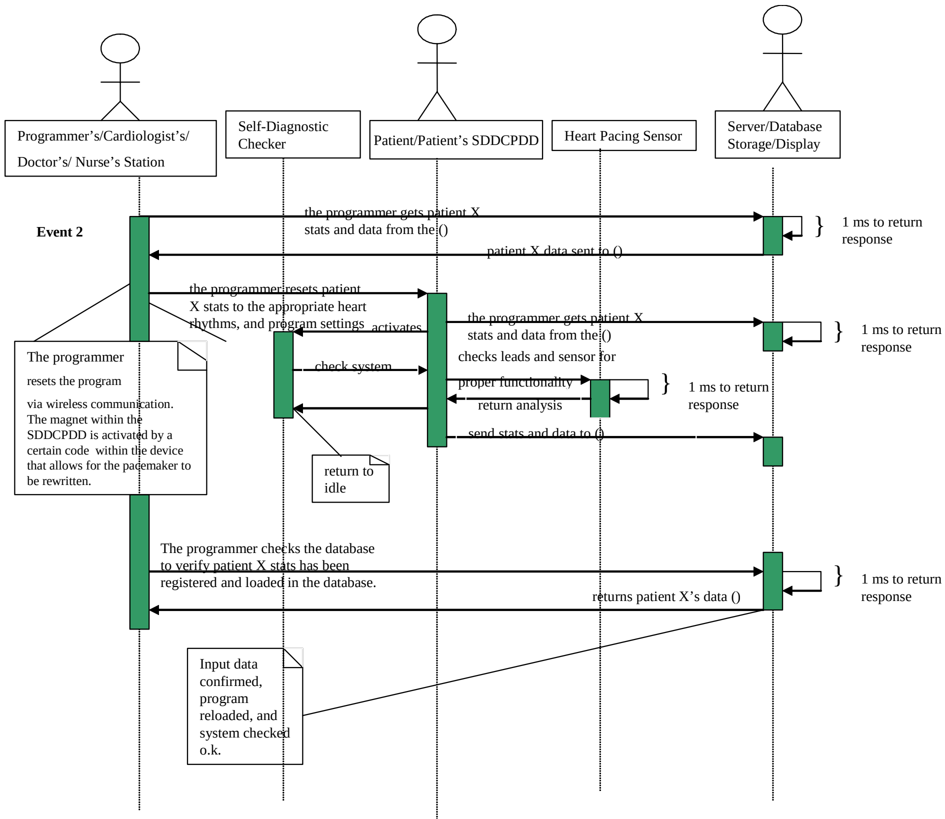


Figure 12. Reprogram SDDCPDD - Sequence Diagram

## E. STRUCTURED QUEING LANGUAGE (SQL)

### 1. Introduction

SQL is used to communicate often with databases. It is also used is to update, retrieve, and store data into a database. ‘According to the American National Standards Institute (ANSI), SQL is the standard language for relational database management systems (RDBMS)’; SQL has the capability of enhancing digital communication interactions for sending and receiving signals. It also has the capacity to address important issues such as data security and data integrity. Data security handles the issues of confidentiality and authorized data access. SQL can allow you to interact with other databases by using common commands such as the ”Select”, “Insert”, “Update”, “Delete”, “Create”, and “Drop” commands. These commands grant you the capability to accomplish all tasks needed to update, retrieve, and store historical data into a database. The DBMS is system-to-system application software therefore:

‘A DBMS is a resource shared among diverse client applications:
(1) Interactive and batch applications
(2) Reporting and analysis tools
(3) Ad hoc query interfaces’.

The goal of the DBMS is to provide effective services to all of its clients. Another goal of the DBMS is to provide overall integrity and security of the database. Object-Relational Wrappers provide an excellent solution to the apparent conflict between the needs of the application and the needs of the DBMS. On the other side, they allow the DBMS to maintain a shared data structure that can service a rich set of application clients. This is accomplished through building wrappers that are specific to each application. In the case of the SDDCPDD proposed device, the database will be used as a go-between between the SDDCPDD and the data warehouse. The information from the database to and from the SDDCPDD will be serialized, tagged, and reference specific to the patient and all of his or her data.

An example of how each patient will be serialized or tagged will be achieved as follows:

sddcpdd_req (request_id, patient_id,request_date,request_time)

patreq_details (patreq_id, reqsted_data, action_tkncode)

The primary wrapper class indicates (csdcpdd_req) that the Pacemaker/Defibrillator device wants to either send or retrieve information to or from the database. The second line indicates that the self-diagnostic digitally controlled pacemaker/defibrillator device requested information.

There are many types of SQL's used in RDBMS. Depending on the usage and type of information you would like to retrieve and store depends on the software application you want to use. Some of the common types of names of SQL used in RDBMS are as follows:

1. Oracle
2. Sybase
3. Microsoft SQL Server
4. Access
5. Ingres
6. Sybase
7. dBase IV
8. Mammoth PostgresSQL

**2. Intended Database for the SDDCPDD Design**

The intended database must be capable of storing, retrieving, updating, uplinking, downloading, and securing sensitive information about a particular individual. The sensitive nature of the device and design requires a data warehouse that can accommodate these features with security and data integrity. The application of choice is PostgresSQL.

PostgresSQL offers several features that are indicative of handling secure data. PostgresSQL is a replicator that uses a distributed Transaction Log system to keep track of updates produced by the Master database. The system allows for multiple Slaves to receive data with updates in either a continuous or batch mode.

PostgresSQL has increased the speed, reliability and supported platforms. It also includes (1) replication of sequences, (2) segregate replicated data, (3) the ability to add empty tables to the replicated tables list without having to perform a MCP_REFRESH (Microsoft Certified Professional_REFRESH), and (4) fix bugs as they are reported by the customers.

An article in PostgresSQL news reported that ‘Mammoth PostgresSQL is a robust, and reliable, SQL-compatible Object Relational Database Management System (ORDBMS). It is designed to give small to medium size businesses the power, performance, and open-standard support they desire’. ‘The Mammoth PostgresSQL Replicator delivers reliability and provides that last missing key feature for 24/7 PostgreSQL usage. Command Prompt, Inc. provides support, custom programming, and services for PostgresSQL.’ Using PostgresSQL with JDBCTunnel provides ‘firewall tunneling to connect to your Java Database Connectivity (JDBC) compatible database using the http protocol. When using the JDBCTunnel/JDBCTunnel Driver there is no need to either open a special firewall port for your client’s database usage, or change your program code. ‘JDBCTunnel can run stand alone or from within your existing web or application server’. The advantage to using this application is the ability to have a more stable, faster, secure way of transferring data over the airways with better security and data integrity. Furthermore it gives you ‘the capability of operating across multiple operating systems such as UNIX, Windows and MAC. It can also be used across several servers such as CodeBase SQL Database Server: Windows 2003, XP, 200 or 2000 Advanced Server, NT Server or Workstations (Java applets using JDC must connect through a web server)’.

Sometimes data stored in data warehouses may not be accessed for days, months, or even years, and as time go on so does the enhancements of possessors, operating systems, and software. These changes could cause problems to the SDDCPDD operational environment. A way of handling this problem is to use encapsulation. Encapsulation permits a method of accessing the original data without data corruption no matter how long this data has been stored. This method has to be in the granularities of the SDDCPDD operation. An article in the Intelligent Enterprise Magazine called Data Webhouse refers to Rothenberg and his views on using encapsulation and emulation to 'recreate old systems, even ones as gnarly as electronic games, and how to 'encapsulate the old data sets along with the metadata we need in order to interpret the data set, as well as the overall specifications for the emulation itself'. This leads to the goal of using a data warehouse/data store.

### 3. Data Warehouse/Data Store

There are many data warehouses/data stores; however the best data warehouse depends on the particular application you plan on using or designing. Data warehouses/stores in this application as in many others will be used as a retrieval and storage container of information.

The data warehouse is subject-oriented and therefore (1) 'separate from the operational systems in the enterprise, and populated by data from these systems, (2) existing entirely for the task of making data available to be interrogated' by users, (3) interrogated on the basis of a standard RDBMS such as Oracle, Access, and other such models, (4) time stamped and associated with a defined period of time, i.e. calendar periods or fiscal reporting periods, (5) subject oriented, most usually on the basis of 'customer', and (6) accessible to users who have a limited knowledge of computer systems or data structures'. The data warehouse/data store data for the SDDCPDD will be used on a basis of keeping track of operational events, driven history and data exchange and storage information. The data store will provide the component of the decision support system that acts as a database for storage of the data that is used in the SDDCPDD systems.

There are problems or pitfalls that go hand in hand when using a data warehouse, RDBMS, and digital communication. The problem is with data integrity and privacy. Data integrity is crucial when medical information is sent digitally.  First, the information has to be checked for parity, serialized or tagged; it also has to be un-interruptible, or impervious to hackers (which is a wishful thinking because, as we know, hackers can find a way into almost any system that transmits or retrieves data).  Data security, integration, and integrity must be insured in the design of the SDDCPDD when messages are sent digitally. ‘HIPAA which is the Health Insurance Portability and Accountability Act mandated a Public Law 104-101 that was enacted on August 21, 1996 to cover the privacy of an individual’s personal medical information becoming public. Sections 261 through 264 of HIPAA require the Secretary of HHS (Health and Human Services) to publicize standards for the electronic exchange, privacy and security of health information.  The Privacy Rule, as well as all the Administrative simplification rules that apply to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA’.  This makes it illegal for this information to be hacked and shared by outsiders.  This information sent from the SDDCPDD must be sent digitally, securely, and free from noise and distortion. This leads to my next discussion on digital communication.

## F. DIGITAL COMMUNICATION

The concept of digital communication and how it applies to the SDDCPDD is interesting and yet still very complex.  Digital communication offers several advantages over analog signals.  For one it offers ‘increased immunity to channel noise and external interference. It offers flexibility of system operation.  It provides a common format for the transmission of different kinds of message signals, whether they be voice, video signals, or computer data. It also can be used to provide improved security of communications through the use of encryption technology.  The other advantage of using digital communication is that it provides a method for allowing the ‘integration of diverse sources of information into a common format.’

Since the signal has to ride on a wave of communication, normally an acoustic wave, or light wave; the signal (input/output information) has to be converted back and forth from analog to digital. Various methods of digital communication within the pacemaker/defibrillator/SDDCPDD/military device have to have a feedback control for data recognition and verification. One of the disadvantages of digital communication as compared to acoustic wave is the problem of fading. Fading is controlled or compensated by either of three methods; frequency diversity, time diversity, or spatial diversity. The method most useful for the SDDCPDD application will be that of frequency diversity with the enhancements of frequency agility.

**Frequency Diversity**

- Frequency diversity is defined as 'transmission and reception in which the same information signal is transmitted and received simultaneously on two or more independently fading carrier frequencies'. Frequency diversity relies on the fact that fading is different at different frequencies. These frequencies are radiated by an antenna, similar to radar on how it emits pulses of EM energy to a distant object. The antenna is very important for transmitting and receiving information.

There are practical limitations associated with frequency diversity. The cost of operating multiple sites is often prohibitive. Frequency management is critical and often difficult to achieve. Failure to manage frequency diversity will result in mutual interference between the radar sites. The practical operating bandwidth when using frequency diversity is also limited.' Frequency agility is a good fix to the random and power consuming method of frequency diversity. Frequency agility has another name and it is that of frequency hopping. Frequency hopping/agility can be used to solve frequency diversity by selecting one band of frequencies that is strong and agile enough to be transmitted across a medium without being interrupted. A method of achieving this is through digital communication control.

The formula for which a signal is sent out via digital communication/control is as follows:

$P_r$ = the power available at the receiver input (dBm)

$P_t$ = Transmitter power output (dBm)

$L_p$ = Free space losses (dBm)

$G_t$ = Transmitter antenna gain (dB)

$G_r$ = Receiver antenna gain (dB)

$L_t$ = Transmission line losses transmit side (dB)

$L_r$ = Transmission line losses receiver side (dB)

$P_r = P_t – L_p + G_t + G_r – L_t – L_r$

There are losses associated with signals being sent via cable or wireless applications. These losses can be calculated to determine the maximum loss and strength of the signal being sent.

The Lp, which is the free space losses, is given by the formula:

$L_p = 32.4 + 20 \log (f) + 20 \log (d)$, where f = frequency and d = distance.

When sending wireless information the antenna chosen has to produce a maximum array factor (AF). The maximum array factor causes the signal from the antenna within the device to be able to transmit enough impedance to reach the receiver while still maintaining a low-level power transfer. A low-level power transfer would allow the signal to be sent to its destination without causing any cell damage or harmful effects to the body. The low-level power transfer is chosen for the SDDCPDD because it offers minimal harmful effects of radiation according the 2 W/kg averaged over 10g of tissue put out by the safety transmission regulation and the FDA. The power delivered to the receiver is known by:

$P_r$ = Powered delivered to the receiver

I = current

R = resistance

V = voltage

$R_{in}$ = Input resistor in the system

$Z_L$ = Load resistor

$R_L$ = (2 $R_{in}$ for max power output)

$P_{max} = V^2_{incicent}/4R_{in}$

Therefore, if $V_{oc}$ (open-circuit voltage) is induced into the antenna terminals, then $Z_{in} = R_{rad} + jX_{in}$ (This is the antenna's impedance), and the impedance to the transmission line feeding the antenna. $A_e$ (Effective area of a receiving antenna as the ratio of the time-average power received) is a measure of the ability of the antenna to extract energy from a passing EM wave. Therefore for max power transfer output (signal from the antenna) the maximum power transfer is $V_{oc}^2/8\ R_{rad}$

$P_r = ½\ V^2_{incicent}/4R_{in}(R_{in})$

This power is known as the incident power wave front effective area, or effective aperture. The physical area also known as the aperture area (surface area of the antenna) can be defined as

$A_e = G\ (λ/4π)$

To calculate the minimum transmitted power needed to send a signal from a device to its destination you would have to know the distance between the transmitting and receiving stations, and the directed gain of the transmitter and receiver.

$G_t$ = Transmission gain

$G_r$ = Receiver gain

$P_r$ = Power received

**Example 1.**

Distance (d) = 100 λ

Transmitter gain = 12.5 dB

Receiver gain = 9 dB

Power received = 2.5 mW,

With all of these factors being given, the scenario is as follows:

For a distance of 100 λ from the transmitting station to the receiving station, and a transmitting device gain of 12.5 dB and a receiving station gain of 9 dB, and if the power to be received is 2.5 mW, what is the transmitted power being sent from the device? To figure out the transmitted power, you would have to rearrange the formula and go through the following method of calculations.

$G_t\,(\text{dB}) = 12.5\,(\text{dB}) = 10 \log^{10} G_{t,}$

$G_t = 10^{1.25} = 17.78$

$G_r = 10^{0.9} = 7.94$

$P_r = G_t\, G_r\, (\lambda/4\pi r)^2\, P_t$

$P_t = 2.5\text{mW}\,(4\pi \times 100\,\lambda/\lambda)^2 * (1/ G_t\, G_r)$

Thus,

$P_t = 27.9\text{ W}$

The calculated transmitted power coming from the device is much higher than the requirement set by the FDA, therefore the SDDCPDD would have to be adjusted. The adjusted transmitted power would have to be done automatically to be an effective part of the design scheme. The adjustment of the gain and signal strength power to achieve maximum safe output less than 2 W/10 g still has to be achieved. If you increase the gain from 12.5 to 25 dB, you would notice that the power transmitted $P_t$ from the SDDCPDD is 1.25 mW, which is much lower than the maximum allowable power that can be transmitted from the device, and yield good results. Notice from the last calculation that there was too much power being transmitted from the device, and this would have caused a violation of the mandate put out by the FDA and FCC. Putting boundary conditions within the SDDCPDD to adjust the power level output will aid the device to function optimally within the constraints of its design. However, if there is a need or emergency, the device may be required to send the maximum power output to the receiver. The control mechanism is critical to ensure all measures are considered before sending signals at a power level higher than EPA, FDA regulations. If you go back to Example 1 you will notice that the power level is 15 times what is required by the signal safety transmission regulation commission and the FDA.

**Example 2.**

Distance (d) = 200 λ

Transmitting Gain = 25 dB

Receiver Gain = 18 dB

Power Received = 5 mW

With all of these factors being given, the scenario is as follows:

If a gain of 25 dB and 18 dB is used for transmitting and receiving a signal between a distance of 200 λ from the transmitting and receiving antenna, and the power to be received is 5 mW, then the minimum transmitted power from the transmitter would be as follows:

$G_t\,(dB) = 25\,(dB) = 10 \log^{10} G_{t,}$

$G_t = 10^{2.5} = 316.2$

$G_r = 10^{1.8} = 63.1$

$P_r = G_t\, G_r\, (\lambda/4\pi r)^2\, P_t$

$P_t = 5mW\, (4\pi \text{ X } 200\, \lambda/\lambda)^2 * (1/ G_t\, G_r)$

Thus,

$P_t = 1.583$ W

This is more reasonable for the amount of power you would want to come out of an antenna from an individual.

The Array Factor (AF) is characteristic of radiated elements directed outward towards some point P to where the summation or total energy and vector sum at the electric field point P can be captured and given by the formula

$E_s = E_{1s} + E_{2s}$

⇨ $j\eta\beta Iodl/4\pi[\cos\theta\, e^{-j\beta r1}/ r1(e^{j\alpha})a_{\theta 1} + \cos\theta\, e^{-j\beta r2}/ r2)a_{\theta 2}]$ in an effort to be received by a receiver. Furthermore, if the value of the phase shift (α) and spacing distance (d) can be adjusted or arranged in such a way as to maximize the AF and then summed, then this could benefit the signal strength and thus the transmitted signal by a factor of

⇨ $AF = \sin(N\psi/2) / \sin(N\psi/2)$ where as $\psi = \beta d \cos\theta + \alpha$. At radiated points where the flux $\psi = 0$ and $\theta = 2\pi$; the maximum radiation directed normal to the axis of the array is at its maximum or what ever gain is sufficient to carry the signal to its destination.

The SDDCPDD would have to have an antenna or device that would allow for the signals to be sent via free space, and at a certain power magnification. Power magnification has a lot to do with the doubling of the range in which you want to send your signal. The 2.4 GHz ISM Frequency Band is becoming the world-wide standard in sending digital signals over the airways, via wireless internet, and cell phones. Since an antenna coming out of the cavity of the chest is unfathomable, other means or methods would have to be investigated to achieve the range needed to send or retrieve digital/wireless information to the database, data warehouse and data store. The 802.11 (IEEE standard) Wireless Network Device or the like is ideal for accomplishing the task of sending signals in free space from the patient pacemaker/defibrillator or SDDCPDD, to the ORDBMS, data warehouse, and all routes back and forth and in between. A very weak signal could and would have to be boosted, and then amplified to allow a weak signal to be transmitted to the transmission station to carry the information back and forth between destinations. Algorithm and frequency hopping is critical for the role in achieving signal amplification. Voltage gain is another factor in achieving signal strength and transmission power. If $A_{v\ SDDCPDD}$ is the voltage gain coming out of the self-diagnostic digitally controlled pacemaker/defibrillator device and the station voltage gain is called $A_{v\ station}$ , then if $A_{v\ SDDCPDD}$ = 10 dB and $A_{v\ station}$ = 100 dB, then the total voltage gain of the SDDCPDD and the station = 10 x 100 = 1000. The decibel equivalent of voltage gain ($A_{v\ total}$) => 1000 = 20 log 1000 = 20 x 3 = 60 (dB). This is the gain needed to get the signal to its destination. Frequency hopping is used by many wireless networking devices and applications, and the 802.11 (IEEE standard) seems to be the best device for the SDDCPDD. The 802.11 (IEEE standard) Wireless Networking device seems to be a better choice over Bluetooth, and HomeRF. The table below provides a comparison of the three.

| **802.11(IEEE** | **Bluetooth** | **HomeRF** |
|---|---|---|
| 2.4 Ghz (ISM band) | 2.4 GHz (ISM band) | 2.4 GHz(ISM band) |
| | Frequency hopping spread | Frequency hopping spread |
| 1 Mb/s | 10 Mb/s | 11 Mb/s (up to 54 Mb/s in |
| Security Bug | | |
| Most expensive | Medium | Least expensive |

**Table 8. Wireless Network Criterion**

The SDDCPDD device, once wireless equipped, will operate like the transmitter/receiver device in the picture below.

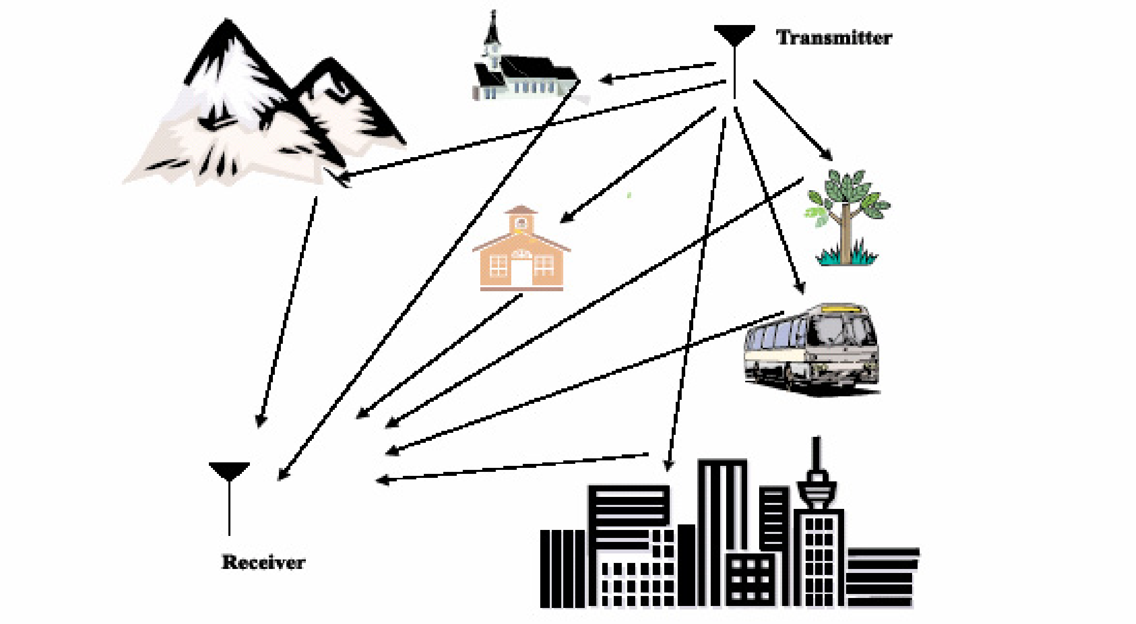


**Figure 13. Simulated SDDCPDD Transmission**

What makes the 802.11x (IEEE Standard) Wireless Device such an attractive device for this application is its ability to apply a method of security in the system. Security means to encrypt and secure disseminated (propagated) packets. Once the packet is encrypted, it can be sent to its host and then checked for verification to be decrypted, and then routed to its appropriate protocol. There are always vulnerabilities to information, and not one bit or byte of information is free from hackers. However, we can make their job labor intensive and exhausting in trying to retrieve the information. One method of not allowing hackers to retrieve your information is to make it difficult for them to get access to the authentication keys (known as authentication spoofing.) If the hacker gets hold of your plaintext along with two cipher-text packets, then the security of the information is violated and the key that goes along with the packets has been discovered, and more than likely he/she or they have infiltrated your system and have access to all your pertinent information.

Authentication is another method that can be used to prevent hackers from retrieving your information. Another method is to have the data encapsulated and check-summed to see if the host verifies that the message that has been sent and encapsulated is all intact. Using PostgresSQL & JDBC lowers the cost and risk of hackers getting hold of your information. This method is cheaper than using an encryption/decryption scheme. However, this method would not be the method of choice for military applications due to the high nature and security risks associated with the mission of military protocols. Hackers or even the enemy getting hold of information could sabotage an operation or mission, which leads to defining which interfaces (COTS/OTS) to use to mate with the system.

# V. SOFTWARE/HARDWARE COMPONENTS AND INTERFACES

## A. COTS/OTS

Commercial-Off-The-Self Items (COTS) and Off-The-Shelf Software (OTS) used for the enhancement and conformance of the design should lower the cost, increase the return on investment, and accessorize the system-development design. COTS and OTS could propose a more innovative, cost-saving solution as opposed to trying to develop the SDDCPDD device/design from scratch. The problem with using COTS/OTS is that you may encounter unexpected hazards, failures, and injuries to the patient as a result of integrating the COTS/OTS into the current system without proper enhancements. COTS may not necessarily have to offer environmental and safety-related documentation to assess the potential hazards or factors contributing to potential risks. Human-based testing will be the preferred method of testing of the SDDCPDD. This would increase the chance of discovering the undiscovered. This would also give the opportunity to examine the interactions being used (source code, system diagnostics checks, serialized data transmission and retrieval), and monitor how all interactions in the design process actually operate.

### 1. Risks Associated with OTS/COTS

The SDCPDD serves as a control function to the ICD system. ‘Most accidents arise in the interfaces and interactions among the components’ The method taken to accomplish the interactions between the device, cardiologists/doctors, patient and SDCPDD will serve as a mechanism to account, control, and assess possible hazards within the pacemaker system. The capabilities and functionality between the software and hardware in the SDDCPDD /pacemaker/defibrillator device lies with the OTS being used and how well testing is conducted before the device becomes implantable. The FDA has a clause that mandates software testing, verification, and validation plans to be conducted before the OTS is to be used or considered to be implantable, viable, and an FDA approved Medical Device.

The ICD and therefore SDDCPDD will have a designed base level secure software kernel within its design mechanism. The secure software kernel within Pacemaker/Defibrillator design detects significant failures of the hardware that surrounds it by a built-in-test or (self-check control scheme) to determine whether or not the device is properly operating and that the incoming/outgoing signals are sensed and whether the encoder/decoder, and processor is functioning properly functioning. This feature was added as a way of detecting critical parameters in the presence of environmental stresses that may degrade performance like that of chemical electrolytes within the body. It also is used to monitor, lead erosion, timed system sequence latencies, and communication anomalies.

### 2. Risk Mitigation Metrics

| Risk | Mitigation Strategy |
|---|---|
| OTS/COTS | Conduct lots of testing between systems, subsystems, and communication devices to ensure and mitigate interoperability between all models |
| Timing Delay | Modeling and Simulation should help with problems that may occur with module testing. |
| Costs | N/A |
| New Technology | Conduct human-based testing (patient). |
| Testing | Concurrent Modeling and Simulation throughout the Process. |
| Real-Time Processing of Information | Conduct testing, isolation of critical and non-critical events, and add a faster processor. |

**Table 9. Risk/Risk Mitigation Scheme**

## B. ISSUES

### 1. Alternative Components

Some of the hardware and software components that are being mentioned in this design are what I have considered as being most desirable. Better or more efficient devices may be used to enhance the design. My research and in-depth study of these different devices indicate that they are likely the most efficient and economical options for what I am trying to accomplish. There is no one method that is better than the next. As most devices in the computer technology age, the design is already obsolete as soon as it comes out on the market.

### 2. Delay Time (Real-Time)

Delay time is also known as latency. Latency is considered as the amount of time it takes for a signal to go from point A to Point B, execute some action, and then send the information (new, add, or the same) back to A. Latency is unavoidable when communicating or poling between sequences of events. Latency is a factor of both software and hardware. 'An executive or operating system that permits the use of interrupts to signal data arrival may have a shorter latency interval than one that uses periodic polling, but underlying hardware constraints prevent the latency from being eliminated completely'. Latency is normal in many applications. However, in the Pacemaker/Defibrillator Device latency can cause a problem if the SDDCPDD goes into a lockout condition. Redundancy, watchdog monitoring, medical care assistance, and control algorithms within the design will enhance the SDDCPDD to ensure safety of the design when latency is an issue. The watchdog timer is added when a critical issue arises and latency becomes a problem. Nancy Leveson gives a good example why redundancy needs to be in the circuit to assist if problems occur with the watchdog timer. Leveson writes 'if a watchdog timer is used to check software, the software should not be responsible for initializing the watchdog, and protection should be provided against the software incorrectly resetting it. An infinite loop in the software routine that resets the watchdog, for example could destroy the ability to detect the software error'. This is why the design constraints of the SDDCPDD allow for parity bit sum-checks to allow for the message being sent to equal the message being received. This way, if for some reason the system has to reset itself, and this may be the case when a run-time error occurs, the system will still get the original information sent and continue operating the device. Since time is critical this function is crucial. Time, critical and crucial are three words that are well-known in military applications and missions.

# VI. RECOMMENDATIONS AND CONCLUSIONS

## A. MILITARY MISSIONS USING THE SDDCPDD DESIGN CONCEPT

The SDDCPDD have several features that I think may be very useful to the Armed Services. The Army in particular could use this device since so many soldiers are being captured and their whereabouts unknown. Even though this device is designed as a pacemaker/defibrillator device; its applications can be used as a sensory data retrieval device for soldiers that have been captured in the field or in combat missions. If the soldiers captured or killed had this application implanted somewhere on their person in a place where their stats could be read, or their whereabouts were known, Special Forces could come and do their job by and infiltrating the enemy camp, and rescuing the prisoners of war with minimal efforts. This device would allow for their stats to indicate if they were deceased, and the rescuers would have the option of retrieving the body right then or coming back and picking it up later. This effort could save many lives from ambush situations.

The military is exploring a device called the Warfighter Physiological Status Monitor (WPSM) that is similar to the device created here in this thesis. My concept is a system level concept of allowing a pacemaker, defibrillator, or other device (SDDCPDD) to become self-diagnostic, individual specific, serialized, and tagged, therefore, allowing stored information within the device to be sent via SQL to a database, data warehouse, and data store to be stored for future reference, statistics, and history of the patient's heart pacemaker/defibrillator activities (natural heart rate, chemical composition, and stimulus demands). It also tackles the concept of digital control, wireless communication, database verification, system safety, and security, and their concept is based strictly on the body, and its stresses (fatigue, mental, heat exhaustion, or respiratory failure).

| | |
|---|---|
| **The Problem of** | **Determining whether or not a soldier is alive, dead, or injured in the field** |
| **Affects** | **The military as a whole** |
| **The result of which** | **Will help eliminate the missing in action (MIA) status of armed service members, and locate injured or distressed soldiers** |
| **A successful solution would** | **Save time and money for search and rescue operations** |

**Table 10. Army Problem Statement**

## B. FEASIBILITY OF THE DESIGN CONCEPT ON THE BATTLE FIELD

This device on the battlefield is possible and likely to be a good investment for future use. If Jessica Lynch and half the other military soldiers and individuals had had a device such as the SDDCPDD on their person during the Iraqi Freedom/Endurance Freedom event, most of them could have been rescued earlier or even saved.

The SDDCPDD or the like would have to be designed and tested based on military specs with military communication requirements as military communication signals have undisclosed frequencies that are different from those used by civilian medical devices. Low frequency is always best to use since everyone is using higher frequencies these days. The problem associated with low frequencies is the power associated with its losses. However, boosters will give the device the extra power levels it needs to process the signal to the receiving point. The signal could also be coupled to provide a higher gain.

## C. CONCLUSIONS AND RECOMMENDATIONS

This thesis explores the concept of using a pacemaker/defibrillator device (SDDCPDD) to store digital information into a data warehouse where it can be collected and analyzed.

The device also explored how SQL, self-diagnostics can be used to help determine faults within the SDDCPDD, and how those faults can be analyzed and help perform functions to interact with the programmer, cardiologist/doctor, nurse's station, patient, data warehouse, and database. It conveys how this device can be used on the battlefield. It also explored how the device can be designed with safety constraints to shield the patient from the harmful effects of radiation given off by the antenna. It showed how COTS and OTS could be used in the constraints of the SDDCPDD to send and receive digital signals from the patient pacemaker/defibrillator device using UML, and OOA/D methods. It also showed how the armed services could use this device to determine the whereabouts of soldiers on the battlefield. The SDCDPDD examined the condition of enhancing the signaling capabilities of the device to encapsulate the data, boost the signal, and carry the information to its destination without being tampered with. It also shows the viability of such a device and how it can be used to minimize casualties, and determine whether or not an individual can be found and rescued on the battlefield if needed.

The knowledge and studying put into this thesis has truly helped me to expand my horizons as I have found a new love in the field of communications, signal strength enhancements and verification. In order for this design concept to mature, more exploration would have to be made, and conducted before a solicitation for money. Human-based testing is the best method to validate, verify, and prove the usefulness of the device before the FDA and FCC would approve such a device. One of the biggest issues found in this thesis is dealing with the antenna coming out of the human body. This may cause discomfort to the patient, and possibly expose him or her to radiation. Testing of the device on an actual person(s) would have to be conducted to assess the viability of the design. What do you think? Is this viable? Will it work?

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## GLOSSARY

ampere - The ampere is the SI unit of current. It is a fundamental unit. It is defined as that constant current which, if maintained in two straight parallel conductors of infinite length, of negligible circular cross-section, and placed 1 meter apart in vacuum, would produce between these conductors a force equal to $2 \times 10^{-7}$ newton per meter of length [1948].

amplitude - maximum or peak value of a quantity or wave varying in an oscillatory manner, measured with respect to the reference.

amplitude modulation (AM) - A process whereby the amplitude of the carrier is controlled by the modulating signal.

analog - The branch of electronics dealing with continuously varying quantities.

analog to digital converter - A/D converter, A to D converter A device or circuit used to convert an analog signal to a digital signal across a pair of terminals.

angular velocity - Rate of rotation about an axis. It is the rate of change of angle with time. It is measured either in revolutions per second, revolutions per minute (r.p.m.) or radians per second (rad/s).

angstrom - A unit used to measure very small lengths, such as wavelength. (Equal to $10^{-10}$ m).

antenna - A device consisting of spaced elements that are used to receive broadcast signals. A system of conductors that radiates and or receives electromagnetic waves (radio waves). Any structure or device used to collect or radiate electromagnetic waves.  A device that converts radio frequency electrical energy to radiated electromagnetic energy and vice versa; in a transmitting station, the device from which radio waves are emitted. [47CFR]

aperture - In a directional antenna, the portion of a plane surface very near the antenna normal to the direction of maximum radiant intensity, through which the major part of the radiation passes. 2. In an acoustic device that launches a sound wave, the passageway, determined by the size of a hole in the inelastic material and the wavelength. [After 2196]Opening. In optical instruments, it is the size of the opening admitting light.

attenuation - Loss of signal power or amplitude suffered during its transmission through a medium.

attenuator - A passive device used to reduce signal strength.

atria - The upper chambers of the heart that pump blood to the lower chamber.

atrial flutter - A condition in which the contractions in the atria becomes extremely rapid.

atrioventricular (AV) Node - A group of cells in the middle of the heart that help maintain a normal heart rhythm and rate. The AV node coordinates the pumping of the atria and ventricles so that they work together to pump blood most efficiency.

automated external defibrillator - An emergency device that uses external paddles to apply a brief high-energy shock to try to stop life-threatening heart rhythms and return the heart to a normal rhythm.

bandpass filter - A filter designed to pass all frequencies within a band of frequencies.

bandwidth - Commonly defined as the difference between the upper and lower frequencies of the half power points of the response relative to the reference frequency. The difference between the two dominant critical frequencies of an amplifier. It is also equal to the upper critical frequency when there is no lower critical frequency. The data a cable can carry measured in bits per second (bps).

bit **-** The unit of information in information theory. The amount of information required to specify one of two alternatives 0 and 1.

byte - *A* group of 8 bits.

biventricular pacing - Pacing both the right and left ventricles simultaneously.

boundary – (1) (Of a system) determined by how events are recognized and responses are delivered. Defines the scope of its development project. (2) In testing, the set of values that limit an input or output domain.

bradycardia - The slowness of the heartbeat.

cardiac arrest - The stopping of the heart beat, usually because of interference with the electrical signal.

cardiac conduction system - The specialized network of electrical cells in the heart that stimulates the heart to beat.

cardiologist - A physician specially trained in the diagnosis and treatment of heart disease.

cardioversion - An external shock or an ICD therapy option used to treat rapid heart rhythms. Cardioversion consists of synchronized shock impulses that may progress from low energy to high energy levels, depending on what is needed to stop the rapid rhythm. Also, restoration of normal sinus rhythm with drug therapy.

cathode ray tube (*CRT)* - An electron-beam tube in which the beam can be focused to a small cross-section on a luminescent screen and varied in both position and intensity to produce a visible pattern. Electric potentials applied to the deflection plates are used to control the position of the beam, and its movement across the screen, in a desired manner.

COTS (Commercial-Off-The-Shelf Items) – Components or complete systems that are offered for sale to the general public. General-purpose components provided to support a wide range of applications. Typically offered for sale by a commercial organization.

complementary metal oxide semiconductor (CMOS) - This technology is typically used in making transistors. The "complementary" part of the term unfortunately does not mean these semiconductors are free. Instead, it refers to how they produce either a positive or negative charge. Because CMOS-based transistors only use one charge at a time, they run efficiently, using up very little power. This is because the charges can stay in one state for a long period of time, allowing the transistor to use little or no power except when needed. Because of their wonderful efficiency, processors that use CMOS-based transistors can run at extremely high speeds without getting too hot and going up in flames. You may also find CMOS memory in your computer, which holds the date and time and other basic system settings. The low power consumption of CMOS allows the memory to be powered by a simple Lithium battery for many years.

conductor - A wire, cable, rod, tube or bus bar designed for the passage of electrical current. An object or substance which conducts electric current.

conservation - Reducing energy consumption and energy waste using a strategy to attain higher efficiency in energy production and utilization, to accommodate behavior to maximize personal welfare in response to changing prices, and shifting from scarce to more plentiful energy resources.

coupling capacitor - A capacitor used to transmit an ac signal from one node to another.

data integrity - A condition in which given data always yield the same result. Data integrity is mandatory in any database.

data store – The component of the decision support system that acts as a database for storage of business data and business model data. The data in the data store has already been extracted and filtered fro the external and operational data, and will be stored for access by the end user query tool for the business data model.

data warehouse – The database design of information organization favored by decision support systems. The data warehouse is an integrated, subject-oriented, time-variant, non-volatile database that provides support for decision making.

database – A computer structure that houses a collection of related data. A database contains two types of data: end user data (raw facts) and metadata. The metadata consist of data about data, that is, the data characteristics and relationships.

database management system (DBMS) - Software that serves as an intermediary between the user and the database. The DBMS translates user requests into computer code that is required to fulfill those requests. A DBMS helps the user manage the data stored within the database.

decibel – A unit used to express relative difference in power or intensity, usually between two acoustic or electric signals, equal to ten times the common logarithm of the ration of the two levels.

defibrillation - A technique in which a brief, high-energy electric shock delivered to the heart to treat life-threatening arrhythmias. This therapy can be used externally with defibrillating paddles or internally from an **ICD.**

digital to analog converter (digital to analog converter or D/A converter or D to A converter) - A device or circuit used to convert a digital signal to an analog signal across a pair of terminals.

distortion - An undesired change in waveform. Distortion is a term that describes abnormal wave shapes.

dual chamber pacing - Pacing in both the atria and the ventricles. Also called physiologic pacing.

charged particle - It is defined as the force acting on a unit positive charge placed at that point.

electric shock - A dangerous physiological effect resulting from the passing of an electric current through a human body or livestock. Injury to the skin or internal organs that results from exposure to an electrical current. Electric shock occurs when the body becomes a part of an electric circuit. The electrical current must enter the body at one point and leave at another. The human body is a good conductor of electricity. Direct contact with electrical current can be potentially fatal. While some electrical shocks may appear not to be serious, there still may be serious internal damage, especially to the heart and brain.

electromagnetic - Relating to a magnetic field created by an electric current.

electromagnetic field - Electric and magnetic force field that surrounds a moving electric charge.

electromagnetic interference (EMI) - A term that describes electrically induced noise or transients, usually at frequencies above 1 MHz.

embedded system - A specialized computer system that is part of a larger system or machine. Typically, an embedded system is housed on a single microprocessor board with the programs stored in ROM. Virtually all appliances that have a digital interface -- watches, microwaves, VCRs, cars -- utilize embedded systems. Some embedded systems include an operating system, but many are so specialized that the entire logic can be implemented as a single program. A combination of hardware and software which together form a component of a larger machine. An example of an embedded system is a microprocessor that controls an automobile engine. An embedded system is designed to run on its own without human intervention, and may be required to respond to events in real time.
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encapsulation – Programming language access control mechanisms that determine visibility of names in and among lexical units. The physical details of a data structure, device interface, or other software component are not visible to other modules. With encapsulation, (1) a component can be used without explicit reference to implementation details, and (2) the programmer is effectively prevented from using the hidden details.
electric field - The electric field is a region in which a force is exerted on a

encoder - A digital circuit that converts information into coded form.

energy - Capacity to do work. [Unit: joule or J]
In the electric power industry, energy is more narrowly defined as electricity supplied over time, expressed in kilowatt-hours.

event – (1) In a state machine, the stimulus that may cause a transisiton. (2) In the FREE state model, either (i) a message sent to the class under test, (ii) a response received from a server or class under test, or (iii) an interrupt or similar external control action that must be accepted by the class under test. An event represents any kind of stimulus that can be presented to an object: a message from a client, a response to a message sent to the virtual machine supporting an object, or the activation of an object b an externally managed interrupt mechanism. Thus an object ma change state (accept an event) without receiving a message from an external client.  (3) In many GUI environments, any externally generated request for service visible to the application program.

fibrillation - Rapid, uncoordinated contractions of individual heart muscle fibers. The heart chamber involved can't contract all at once and pumps blood ineffectively, if at all.

flutter - A condition in which the contractions in the upper or lower chambers of the heart becomes extremely rapid.

gain - A measure of amplification of a device, usually expressed in dB.

gauss - An old unit for measuring magnetic flux density (or magnetic induction). (1 G (unit) = $10^{-4}$ T)

gigawatt - Unit of electric power equal to one billion watt, or one thousand megawatt.

ground - A conducting connection, either intentional or accidental, between an electric circuit or equipment and the Earth or some conducting body serving in place of the Earth.

hacker – One who is proficient at using or programming a computer, a computer buff. One who illegally enter another’s electronic system, as to gain secret information.

hardware – The computer and components proper.
heart monitor - A device used to record activity of the heart for diagnosis purposes.

heart rate/rhythms - also called arrhythmias is a condition that occurs when the normal rhythms become sporadic or even stop.

hertz  - (Hz) SI unit of frequency. One hertz is equal to one cycle per second.

ICD - Abbreviation for implantable cardioverter-defibrillator. A pager-sized, implanted version of an external defibrillator used to treat abnormally rapid heart rhythms. It can deliver several types of therapies, including   cardioversion, defibrillation, antitachycardia pacing and bradycardia pacing. In most impulse generators, certain capacitors are charged in parallel through high series resistances, and then discharged through a combination of resistors and capacitors, giving rise to the required surge waveform (usually double exponential) across the test device.

impulse response - Behaviour of a circuit when the excitation is the unit impulse function. The excitation function may be a voltage or a current.

infrared radiation - Optical radiation for which the wavelengths are longer than those for visible radiation and shorter than those for radio waves. It corresponds to invisible heat radiation.

insertable loop recorder - A small, implantable cardiac monitor that continuously records the heart rhythm in a "loop" for up to 14 months; used to diagnose spontaneous, infrequent syncope.

insulation - Suitable non conductive material enclosing, surrounding or supporting a conductor.

insulation failure - Fault between the phase conductor and non-current carrying metallic parts of an electrical equipment, as a result of which high voltages may appear on the frames of equipment and may be dangerous to a person coming in contact with it.

interpolation - A process of filling in intermediate values or terms between known values or terms.

isolation - The degree to which a device can separate the electrical environment of its input from its output, while allowing the desired transmission to pass across the separation. A function intended to cut off for reasons of safety the supply from all, or a discrete section, of the installation by separating the installation or section from every source of electrical energy.

interoperability - The relative ease or difficulty of (1) getting the output of one system accepted as input by another system and (2) once accepted, having it interpreted and processed correctly.

joules – The unit of power in the System International (SI) system is J/s (Joules/second), which is also called a watt. Joule (J) SI unit of work or energy. One joule is defined to be the work done by a force of one Newton acting to move an object through a distance of one meter in the direction in which the force is applied.

kilowatt-hour (kWh) - The standard unit of electricity supplied to the consumer. Equal to 1 kilowatt acting for 1 hour. 1 kWh = 3.60 x 106 J

Kirchoff's current law - KCL States that the algebraic sum of the currents entering a node (or a closed boundary) is zero.

Kirchoff's voltage law - KVL States that the algebraic sum of the voltages around a closed loop is zero.

local area network (LAN) – A network of computers that spans small area, such as single building. A LAN allows end user personal computers to share files via a central personal computer that acts as a network file server. With a LAN, multiple users can also share devices, such as printers. A data communications system confined to a certain area. The area served may consist of a single building, or a cluster of buildings.

leads - A long flexible wire or conductor attached to an Electrocardiograph machine. These wires/conductors are attached to the body to obtain a record of the electrical activity of the heart during a procedure known as an *Electrocardiogram* or ECG.

losses - The general term applied to energy (kWh) and capacity (kW) lost in the operation of an electric system. Losses occur principally as energy transformations from kWh to waste-heat in electrical conductors and apparatus. This power expended without accomplishing useful work occurs primarily on the transmission and distribution systems.

magnetic field - A region of space that surrounds a moving electrical charge or a magnetic pole, in which the electrical charge or magnetic pole experiences a force that is above the electrostatic ones associated with particles at rest.

magnetic flux - A measure of quantity of magnetism, taking account of the strength and the extent of a magnetic field. [Unit: weber]

magnetic shield - A piece of magnetic material used to carry the magnetic flux around an object to prevent the object from being affected by the magnetic field.

microwave - Electromagnetic radiation with wavelengths ranging from very short radio waves to almost infrared region. Wavelengths from 300 mm to 1 mm.

modulator - The process of varying some characteristic of one wave (carrier wave) in accordance with some characteristic of another wave.

noise - An unwanted random signal (in the form of a voltage or current) in an electrical circuit making the information more difficult to identify.

normal heart rhythm (Sinus Rhythm) - The normal beating of the heart, as regulated by the sinoatrial node (SA node); approximately 60-80 beats per minute. Also called normal sinus rhythm.

object-oriented analysis (OOA) – OOA is concerned with developing software engineering requirements and specifications that expressed as a system's object model (which is composed of a population of interacting objects), as opposed to the traditional data or functional views of systems. OOA can yield the following benefits: maintainability through simplified mapping to the real world, which provides for less analysis effort, less complexity in system design, and easier verification by the user; reusability of the analysis artifacts which saves time and costs; and depending on the analysis method and programming language, productivity gains through direct mapping to features of Object-Oriented Programming Languages [Baudoin 96].

object-oriented design (OOD) is concerned with developing an object-oriented model of a software system to implement the identified requirements. Many OOD methods have been described since the late 1980s. The most popular OOD methods include Booch, Buhr, Wasserman, and the HOOD method developed by the European Space Agency [Baudoin 96]. OOD can yield the following benefits: *maintainability* through simplified mapping to the problem domain, which provides for less analysis effort, less complexity in system design, and easier verification by the user; *reusability* of the design artifacts, which saves time and costs; and productivity gains through direct mapping to features of Object-Oriented Programming Languages [Baudoin 96].

Object/Relational Database Management System (O/RDBMS) – A data model based on the ERDM which includes many of the OO model's best features within an inherently simpler relational database structural environment.

Off-The-Shelf Software (OTS software) – A generally available software component, used by a medical device manufacturer for which the manufacturer can not claim complete software life cycle control.

pacemaker - A small, implantable device that provides an electrical stimulus to the heart when the natural electrical signal is absent or too slow. when the natural rate is too slow to provide sufficient pumping action.

pacing - Stimulating the heart to increase its rate.

parity bit - An additional bit that is attached to each code group so that the total number of 1s being transmitted is either odd or even.

passive fixation - The tined-like mechanism at the tip of a pacemaker lead that attaches the lead(s) to the inner surface of the heart.

period - Duration between repetitions of a waveform cycle. It is also equal to the inverse of frequency).

permeability - A measure of how easily magnetic lines of force can pass through a material. The permeability of a material is defined as the constant of

proportionality between the magnetic flux density and the magnetic field. It is a constant for a given magnetic material in the linear region.
permeability of free space (µo) = 8.854 x 10-12 F/m

permeance - Inverse of reluctance. [Unit: H]

permittivity - The permittivity of a material is defined as the constant of proportionality between the electric flux density and the electric field. It is a constant for a given dielectric.

permittivity of free space (µo) = 4 x 10-7 H/m
positive feedback - Feedback where the returning signal aids the effect of the input signal.

power - Is the time rate of consuming or absorbing energy. [Unit: watt or W]
power. The active component of power in an alternating circuit is usually referred to as power or active power. [Unit: watt or W]

power dissipation - The amount of power that is consumed and converted to heat.

programmer (device) - A special computer that allows a health care professional interacts with a pacemaker or defibrillator system by means of radio waves. The programmer is used to assess all the operating functions of the pacemaker and/or *ICD* system.

programmer – one who programs, esp. one who writes computer programs.
protocol – A specific set of rules to accomplish a specific function. In the object-oriented data model, protocol refers to a collection of messages to which an object responds.

pulse amplitude modulation (PAM) - Regularly spaced rectangular pulses vary with instantaneous sample of an analog message signal in a one-to one fashion as the amplitude of the carrier is controlled by the modulating signal.

pulse generator - A small implantable device that is used to stimulate the heart to beat when it is too slow.

quadrature amplitude modulation (QAM) – Quadrature amplitude modulation is also known as quadrature-carrier multiplexing and it enables two double-sideband suppressed-carrier (DSBSC) modulated waves (resulting from the application of two independent message signals) to occupy the same transmission bandwidth, and yet it allows for the separation of the two message signals at the receiver output.

radio frequency (RF) ablation - Treatment for abnormal heart rhythms.

Catheters or special wires that can be placed in the heart to record its activity are inserted into the large blood vessels of the groin and guided into the heart. A special machine is then used to direct high frequency electrical energy into the tiny areas of the heart muscle that cause the abnormal rhythms. The special energy destroys the abnormal electrical pathways causing the abnormal rhythm, but leaves the normal pathways in place.

radiation - RF energy which is emitted or leaks from a distribution system and travels through space. These signals often cause interference with other communication services.

radio-frequency interference (RFI) - Electromagnetic signals of a frequency associated with electromagnetic radiation which are coupled to a conductor either directly or as with an antenna.

radio frequency energy - This is the specific kind of energy used in radio frequency ablations to disrupt a portion of the circuit that allows certain arrhythmias to continue.

rate responsive pacing – Pacing in which the rate is altered in response to the changes in activity levels of the body to meet the demand for increased circulation. Many pacemakers and ICD have special sensors to respond to the patient's activity requirements.

real-time – A real-time system is required to perform its function within the specified time constraints.

receiver - The part of a communications system which converts electrical waves into visible or audible form.

redundancy - Duplication of elements in a system or installation to enhance the reliability or continuity of operation.

relational Database Management System (RDBMS) – A collection of programs that manages the complexity of a relational database. The RDBMS software translates the user’s logical requests (queries) into commands that physically locate and retrieve the requested data. A good RDBMS also creates and maintains a data dictionary (system catalog) to help provide data security, data integrity, concurrent access, easy access, and system administration to the data in the database through a query language (SQL) and application programs.

relative permeability - Ratio of the permeability of the magnetic material to that of free space. The permeability of free space is $4 \times 10^{-7}$ H/m. The permeability of air is very nearly equal to the permeability of free space.

relative permittivity - Ratio of the permittivity of the dielectric material to that of free space. The permittivity of free space is $8.854 \times 10^{-12}$ F/m. The permittivity of air is very nearly equal to the permittivity of free space.

refractory period - A period of time during which heart muscle is resistant to stimulation.

reliability - The guarantee of system performance at all times and under all reasonable conditions to assure constancy, quality, adequacy and economy of electricity. It is also the assurance of a continuous supply of electricity for customers at the proper voltage and frequency. Electric system reliability has two components - adequacy and security. Adequacy is the ability of the electric system to supply the aggregate electric demand and energy requirements of the consumers at all times, taking into account scheduled and unscheduled outages of system facilities.

resonance - A condition in which a quantity reaches maximum value. In electrical circuits, it is a condition in an RLC circuit in which the magnitude of the voltage or the current becomes a maximum or the circuit becomes purely resistive.

risk – A measure of the probability and consequences of an unsatisfactory outcome.

robust – Said of a system that is failure and fault tolerant, and supports systems management in a straightforward, efficient, and cohesive manner. A system that handles unexpected states in a way to minimize performance degradation, data corruption, incorrect output, and abends.

scope – The collection of software components to be verified. Since tests must be run on an executable software entity, scope is typically defined to correspond to some executable component or system of components. (2) The level of abstraction represented in a state machine. It ma be bounded (only abstract values of state variables are considered) or recursive (all levels of abstraction are flattened until only primitive data types remain). (3) In a program, the names visible for a given lexical unit. (4) In project management, the boundary of the work assignment, or the project goals.

security - is the ability of the electric system to withstand sudden disturbances such as electric short circuits, infiltration, or unanticipated loss of system facilities.

sensing - The monitoring function of the pacemaker system that allows the device to detect the heart's natural electrical activity.

sequential pacing - Replication of the heart's electrical conduction from atria to ventricles simulates normal conduction.

server – Any process that provides requested services to clients.

SI units - The International System of Units.

shielding - The process of shielding pieces of apparatus from the effect of electrostatic fields which are external to the apparatus itself. Protective coating that helps eliminate electromagnetic and radio frequency interference.

signal - A visual, audible, electrical or other indication used to convey information.

signal-to-noise ratio (S/N ratio) - The ratio of desired signal level to the undesired noise level, expressed in dB.

speed of light - speed of light in vacuum (co) = 2.997 925 x 108 m s-1
spike - A spike involves a sudden marked jump in voltage, which can damage electronics and corrupt or destroy data.

single chamber pacing - One type of cardiac device (e.g. Single Chamber/ Pacemaker), that operates with the lead located in the atrium or ventricle.

sinoatrial (SA) Node **-** The heart's natural pacemaker. A group of cells located in the right atrium that sends out electrical signals to make the heart pump. The signals travel from the SA node through the atrioventricular (AV) node, and then to the lower chambers of the heart.

software – The operating system, utilities, files, file management programs, and application programs that generate reports from the data stored in the files.

structured query language (SQL) – A powerful and flexible relational database software language composed of commands that enable users to create database and table structures, perform various types of data manipulation and data administration, and query the database to extract useful information.

ultra high frequency (UHF) - Radio frequencies in the range 300 MHz to 3000 MHz.

uncertainties - Uncertainties are factors over which the utility has little or no foreknowledge, and include load growth, fuel prices, or regulatory changes. Uncertainties are modeled in a probabilistic manner. However, in the Detailed Workbook, you may find it is more convenient to treat uncertainties as "unknown but bounded" variables without assuming a probabilistic structure. A specified uncertainty is a specific value taken on by an uncertainty factor (e.g. 3 percent per year for load growth). A future uncertainty is a combination of specified uncertainties (e.g. 3 percent per year load growth, 1 percent per year real coal and oil price escalation, and 2.5 percent increase in housing starts).

unified modeling language (UML) – A general-purpose modeling language that describes the static structure and dynamic behavior of a system. It is not a design method or a development process.

ventricles - The two lower chambers of the heart.

ventricular fibrillation (VF) - A heart rhythm disorder that originates in the ventricles. VF is an abnormally rapid heart rhythm that is highly unstable and irregular. During VF, electrical signals move chaotically through the heart, preventing it from pumping blood and beating properly. This often results in loss of consciousness. If left untreated, it may result in sudden cardiac death.

ventricular tachycardia (VT) - A heart rhythm disorder that originates in the ventricles. VT is a rapid rhythm during which patients may feel faint or dizzy, or even pass out.  During VT, the heart does not pump blood as efficiently as it does during a normal rhythm because rapid contractions prevent it from filling adequately with blood between beats. VT can be dangerous, even life-threatening, if not properly treated.

watt (W) - SI unit of power. One watt is equal to a power rate of one joule of work per second of time.

weber (Wb) - SI unit of magnetic flux. One weber is equal to the magnetic flux which, linking a circuit of one turn would produce in it an electromotive force of 1 V if it were reduced to zero at a uniform rate of 1 s.

wide area network (WAN) – Network type used to connect computer users across and between countries; generally makes use of telephone or specialized communications companies.

wireless communication – Media, such as satellite and radio, used for networking computers as an alternative to cables.  Steadily gaining popularity for connecting remote sites, it is considered the potential future replacement for conventional cables.

wireless LAN (WLAN) – A local area network that is connected by wireless technology rather than wires.

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